UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CYTYC CORPORATION Applicant, v. DEKA PRODUCTS LIMITED PARTNERSHIP, Respondent.	CIVIL ACTION NO. 05-10932-WGY

DEKA PRODUCTS LIMITED PARTNERSHIP'S MEMORANDUM IN SUPPORT OF ITS APPLICATION TO CONFIRM ARBITRATION AWARD AND IN OPPOSITION TO CYTYC'S APPLICATION TO VACATE AWARD

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Dated: May 19, 2005

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INTRODUCTION

After a three-day hearing and after the submission of over 400 exhibits, the testimony of 12 witnesses, and over 200 pages of briefs, an arbitration panel of distinguished jurists found that Cytyc Corporation breached a license agreement with DEKA Products Limited Partnership. In particular, the Panel based its decision on key provisions of the agreement:

> The central issues in this arbitration are what is meant by "Products and Improvements" and how should a royalty "equal to one percent (1%) of the Net Sales" be calculated.

Exh. 1, Partial Final Award at 1. As shown below, these are the very same issues that Cytyc itself submitted to the Panel. Cytyc asked the Panel to construe certain terms, and the Panel did just that, never straying from the task at hand. Because the Panel fairly interpreted those terms, this Court must confirm the award and deny Cytyc's application to vacate it.

In effect, Cytyc asks this Court to second-guess the Panel, to reweigh the evidence and interpret the agreement anew. Under the very narrow standard of review for arbitrations, this Court may not do so. So long as the Panel has even arguably construed the relevant contractual provisions, a court must confirm the resulting award. Here, the Panel rooted its decision in the very provisions that Cytyc itself identified. Thus, this Court must confirm the award.

DEKA'S CONTRIBUTIONS ENABLED THE THINPREP SYSTEM

DEKA is a research, design, and development laboratory that helps other companies develop new products or improve existing ones. DEKA focuses mainly on medical devices but has also invented other products, such as the much-publicized Segway Human Transporter. The United States Patent & Trademark Office recently recognized DEKA's founder, Dean Kamen, as "one of the world's best known and most successful inventors." *See* **Exh. 4**, Print-out from USPTO web site; **Exh. 5**, Hearing Day 1 at 63-72 (testimony on DEKA's history).

The relationship between DEKA and Cytyc began in the fall of 1988, when Cytyc's founder, Stan Lapidus, sought Kamen's help with an engineering problem. Lapidus explained that he was developing machine vision (*i.e.*, computer imaging) equipment to read Pap smear slides used for cervical cancer screening. But to make the machine vision work, Lapidus needed a way to deposit a thin, uniform layer of cervical cells onto the slide, without the clumps of cells, blood, and mucus that would otherwise obscure the sample if the slide were prepared in the conventional way, by hand. Lapidus had failed to solve that problem and therefore asked Kamen if he could solve it. **Exh. 5,** Hearing Vol. 1 at 83-91; **Exh. 8**, Lapidus depo. at 10.

Kamen responded, "You're right. I do know how to solve this problem." **Exh. 5**, Hearing Day 1 at 90. Kamen explained to Lapidus that DEKA's patented "FMS" technology could be adapted to enable an automated slide preparation system.[1] Lapidus loved Kamen's idea and asked Kamen to develop such a system. Thereafter, DEKA worked to develop what became the ThinPrep system. **Exh. 5,** Hearing Vol. 1 at 91-95; **Exh. 8**, Lapidus depo. at 16-17.

Preparing a slide for testing requires (1) a slide preparation machine and (2) a test kit of certain disposable parts--including a filter cylinder, a vial of collection fluid, a collection device, and a microscope slide. The Panel found that, contrary to Cytyc's assertion that Lapidus alone invented the ThinPrep system, "the development of the ThinPrep system was a collaborative

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[1] FMS stands for "Fluid Management System," which is an ultra-sensitive pumping technology that precisely monitors and controls fluid flow. FMS allows the system to draw cells suspended in a fluid up against a filter and then to sense when one thin, complete layer of cells has clogged the filter pores. The system then deposits that layer of cells onto the slide. **Exh. 5,** Hearing Day 1 at 97-100. The fluid that the ThinPrep system uses in this process is the preservative fluid containing the patient's cell sample. Thus, contrary to Cytyc's assertion, the vial of fluid is part and parcel of a system designed to control fluid flow. Indeed, Mr. Kamen, "can't imagine how you use FMS, Fluid Management System, without fluid. How do you make a slide without the sample? I believe that's obviously an important piece of it." *Id.* at 136.

effort and that indeed the 'key' component of that system was the FMS technology." **Exh. 1**, Partial Final Award at 2. The License Agreement thus recognizes DEKA's contribution:

> DEKA has developed the Products, and Cytyc hereby acknowledges that the Products' concept and design are acceptable to Cytyc and that DEKA has fully performed all research and development and all other obligations to Cytyc.

Exh. 3, License Agreement at § 5.01.

Cytyc's Stan Lapidus emphasized that DEKA's inventive contribution was "extremely important," "invaluable," and "essential" for the implementation of the ThinPrep system. **Exh. 8**, Lapidus depo. at 39-40, 96-97. Even Cytyc's own engineers admit that the ThinPrep system depends on, and would not work without, FMS. *See* **Exh. 9**, Vartanian depo. at 114-115.

DEKA PROVED THAT CYTYC UNDERPAID ROYALTIES

In 1993, DEKA and Cytyc signed an agreement (the "License Agreement") under which Cytyc agreed to pay royalties on products enabled by DEKA's patented FMS Technology and other inventive contributions--namely, on Cytyc's ThinPrep system.

In November 2001, Cytyc failed to make its quarterly royalty payment and sent DEKA a letter alleging that it had overpaid royalties and that, therefore, Cytyc would deduct royalties to cover the overpayment. DEKA investigated and discovered that Cytyc had significantly underpaid royalties. DEKA also learned that Cytyc had hidden that underpayment through a variety of deceptive accounting schemes, including one now known as the "relative cost ratio" scheme.[2] Cytyc devised these schemes to reduce royalties by applying a ratio that apportions royalties to the filter cylinder alone and substantially diminishes the true value of even that item.

[2] Under the "relative cost ratio" scheme, Cytyc applies a ratio of the manufacturing cost of the filter cylinder to the manufacturing cost of the entire kit of disposables. The License Agreement, however, bases royalties on "Net Sales" (*i.e.*, price) of the product, not on its cost.

Cytyc unilaterally chose this "relative cost ratio" scheme and, moreover, changed its method for calculating royalties several times, without ever consulting DEKA:

> MR. BROMBERG: That method got changed. It certainly got changed in '96, and then it got changed again, in our view, in '98, and then again in 2001.
>
> ARBITRATOR MERHIGE: By the consent of both parties?
>
> MR. BROMBERG: No. It was done unilaterally without notice.
>
> ARBITRATOR MERHIGE: Without even telling them.
>
> MR. BROMBERG: Without even telling them. And I might add, Your Honor, without providing any description or explanation of how the royalties were being computed.
>
> ARBITRATOR MERHIGE: I don't want to hit you with something. Just for a guy who knows little about it, that sounds unfair.

Exh. 5, Hearing Day 1 at 21-22.[3]

The parties' 1993 agreement contains an arbitration clause providing that all disputes arising out of the agreement must be resolved in arbitration, under American Arbitration Association rules. **Exh. 3**, License Agreement at § 12.1. DEKA therefore filed the underlying arbitration, under AAA rules, in November 2003.

Under AAA procedures, the parties agreed on three neutral arbitrators, all retired judges. Judge E. Leo Milonas, a prominent New York state court judge and now a partner at Pillsbury Winthrop in New York City, chaired the arbitration panel. The other two arbitrators were Judge Vincent L. McKusick, formerly Chief Justice of the Maine Supreme Court and now *Of Counsel*

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[3] Cytyc's argument concerning the speculative impact of Judge Merhige's passing is unseemly. Cytyc cannot presume to know how Judge Merhige would have voted. Indeed, as seen above, Judge Merhige criticized Cytyc's conduct. For the record, however, Judge Merhige presided at the final hearing and participated throughout the arbitration. He died two months after the hearing and after the parties had filed post-hearing briefs. After he died, the surviving arbitrators asked for the parties' input on how to proceed. **Exh. 10**. AAA Rule R-19(b) provides that when a vacancy in the arbitration panel occurs "after the hearings have commenced, the remaining arbitrator or arbitrators may continue with the hearing and determination of the controversy, unless the parties agree otherwise." Neither party raised an objection. Indeed, both parties agreed to put the case in the hands of the surviving panelists. *See* **Exh. 11** and **12**.

at Piece Atwood in Portland, and Judge Robert R. Merhige, Jr., formerly a federal judge in the Eastern District of Virginia and, until his death in February, *Of Counsel* at Hunton & Williams in Richmond, VA. As long-time judges, all three arbitrators had substantial experience trying cases, interpreting contracts, and resolving disputes.

The final hearing was held December 13-15, 2004. Although the parties' arbitration clause requires arbitration in Manchester, N.H., the parties agreed in writing to proceed here in Boston. **Exh. 13,** Stipulated Scheduling Order. At the hearing, the parties examined and cross-examined seven witnesses, submitted 423 exhibits, and otherwise tried the case like any court litigation. After the hearing, the parties filed 40-page briefs, submitted additional exhibits and deposition testimony, and then filed reply briefs. The Panel then requested more argument and evidence on certain subjects, and the parties submitted additional briefs and responses.

On March 7, 2005, the Panel issued its "Partial Final Award" (Exh. 1), holding that Cytyc had breached the License Agreement by (a) failing to pay royalties on all disposables and (b) using the "relative cost ratio" scheme. The Panel then requested further briefing on the calculation of damages and interest, and the parties briefed those issues. On April 26, 2005, the Panel issued the "Final Award" (Exh. 2), awarding DEKA over $7.5 million in unpaid royalties, $563,645 in prejudgment interest through April, and $1 million in legal fees and costs.

The Panel heard evidence concerning Cytyc's poor treatment of DEKA. For example, Cytyc threatened that, if DEKA continued to investigate the royalty underpayments, Cytyc would "manipulate" the financial data to artificially lower the royalties. **Exh. 6,** Hearing Day 2 at 90-91, 160. But the Panel did not base its decision on such egregiousness. As seen below, the Panel's decision centered on the parties' rights and duties under the License Agreement.

ARGUMENT

Review of an arbitration award is "extremely narrow and exceedingly deferential." *Bull HN Info. Sys., Inc. v. Hutson*, 229 F.3d 321, 330 (1st Cir. 2000) (reversing vacatur because court failed to give proper deference to arbitrator) (citation omitted). As such, arbitration awards "are nearly impervious to judicial oversight." *Id.* (citation omitted); *see also Gupta v. Cisco Sys., Inc.*, 274 F.3d 1, 3 (1st Cir. 2001) ("judicial review of an arbitration award is among the narrowest known to the law") (citation omitted). Even if a court disagrees with an arbitrator's contract interpretation, it still may not overturn the decision or reconsider the merits. *Bull HN Info. Sys.* 229 F.3d at 330; *Gupta*, 274 F.3d at 3 ("we will affirm the arbitrator's interpretation of the [contract] if it is in any way plausible, even if we think she committed serious error").

The First Circuit has neatly summarized these constraints on judicial review of arbitration awards and the latitude afforded to arbitrators when they construe contracts:

> We do not sit as a court of appeal to hear claims of factual or legal error by an arbitrator or to consider the merits of the award. We cannot vacate the award because the arbitrator misreads the contract, where there is room to do so, nor are we authorized to reject his honest judgment as to the appropriate remedy, if the contract gives him authority to decide that question. As long as the arbitrator is even arguably construing or applying the contract and acting within the scope of his authority, that a court is convinced he committed serious error does not suffice to overturn his decision.

Challenger Caribbean Corp. v. Union General de Trabajadores de Puerto Rico, 903 F.2d 857, 860-61 (1st Cir. 1990) (citations and internal quotes omitted).

I. THE PANEL FOCUSED ON THE LICENSE AGREEMENT

The dispute, as Cytyc pointed out to the Panel, centered on the definition of "Product Disposable." The Panel therefore rooted its decision in its construction of just this term:

> . . . The License Agreement defines "Products" to include "Product Hardware" and "Product Disposables." Product Disposables means any filter cylinder or similar disposable utilizing Cytyc and/or FMS Technology. The four disposables

> are systematically integrated by design and function in order to work and in order to be patentable.
>
> The phrase "or similar disposable provided such disposable utilizes the Cytyc Technology, the FMS Technology or both" cannot be read to be restricted to only the filter. The very next sentence, which reads "Product Disposable presently includes (emphasis supplied) Cytyc's 'TransCyt Filters'," must mean that the term "Disposables" includes the other disposables in the Kit and any improvements or modifications.

Partial Final Award at 2.

Cytyc itself asked the Panel to construe "Product Disposables." *See* Cytyc's Post-Hearing Brief [attached to Cytyc's motion to vacate] at 2 ("Accordingly, resolution of DEKA's breach of contract claim requires construction of a single provision of the Agreement--the definition of Product Disposables"). And that is exactly what the Panel did. Thus, this Court may confirm the award on this fact alone. *See, e.g.*, *Bull HN Info. Sys.*, 229 F.3d at 332 (award confirmed because the arbitrator construed the provision that the parties submitted to him).

II. THE PANEL CORRECTLY CONSTRUED THE AGREEMENT

Although a court may not reconsider the underlying merits or interpret the contract anew, this Court may take comfort in the fact that the Panel had ample grounds for reading the License Agreement as it did. As shown below, the words of the License Agreement and the parties' dealings support the Panel's finding. Because the Panel had before it a substantial record on the parties' intent, it cannot be said that the Panel erred. "This is not a case of basing a decision only on incredible evidence and public policy." *Local 1445, United Food and Commercial Workers Int'l Union v. Stop & Shop Cos.*, 776 F.2d 19, 22 (1st Cir. 1985) (affirming award because arbitrator based decision on his reading of an ambiguous but controlling contract term).

A. The Agreement, By Its Words, Applies to All Disposables

The royalty for use of DEKA's technology is based on "Products or Improvements." License Agreement at § 3.01. The term "Products" includes "Product Disposables and Product

Hardware." Id. at § 1.01(i). "Product Disposables," in turn, means "any filter cylinder or similar disposable provided such disposable utilizes the Cytyc Technology, the FMS Technology or both." **Exh. 3,** License Agreement at § 1(g) (emphasis added).

Of note, the definition of "Products" does not read, for example, "Product Hardware and *filter cylinders*." Rather, the term uses the broader, generic "Disposables," showing that the term cannot be read as limited to just the filter cylinder. Rather, this broad term must mean any disposable component used for preparing a slide. Indeed, "Product Disposables" includes not just the filter cylinder but also any "similar disposable provided such disposable utilizes the Cytyc Technology, the FMS Technology or both." *Id.* at § 1.01(g) (emphasis added).[4]

In other words, if a disposable utilizes FMS Technology and/or Cytyc Technology in the slide making process, it qualifies as a "similar disposable." Mr. Kamen agrees. *See* **Exh. 5,** Hearing Day 1 at 211 ("Well, it's certainly similar if you're using it to make a slide"). For example, the preservative fluid is used in ThinPrep process--it caries the cervical cells and is utilized by FMS Technology to control the process. So naturally, the vial of fluid is, under § 1.01(g), a "disposable [that] utilizes the Cytyc Technology, the FMS Technology or both."

The Panel acknowledged this wording, finding that all four disposables--filter cylinder, fluid vial, collection device, and slide--are "similar" because they utilize DEKA's technology. Partial Final Award at 2 ("The four disposables are systematically integrated by design and

[4] "Similar disposables" does not mean new versions of filter cylinders, as Cytyc has argued. That is what the term "Improvements" covers. "Improvements" is broadly defined in § 1.01(d) to mean modifications, alterations, and the like that "perform the same or a substantially similar purpose as the Products." The royalty is due on "Products or Improvements," so it would be redundant to define "similar disposables" as just an improved filter cylinder. Similar disposables, therefore, must mean any other component, in addition to the filter cylinder, that utilizes FMS Technology, Cytyc Technology, or both, to make a slide. "Cytyc Technology" is broadly defined and includes the method for preparing a slide that DEKA helped develop, as reflected in U.S. Patent 5,185,084 (**Exh. 14**), which lists Mr. Kamen as a co-inventor.

function" to work together for preparing sample slides). This Court must accept these findings. *Wonderland Greyhound Park, Inc., v. Autotote Sys., Inc.*, 274 F.3d 34, 36-37 (1st Cir. 2002) (Arbitrators' findings are "not open to judicial challenge").

Support for the Panel's finding that all disposables are "similar" appears throughout the record. For example, as the technology licensing expert, Robert Goldscheider, explained,

> The words "similar disposables" are crucial in this case. They've been mentioned by the attorneys; they've been mentioned by the witnesses. And if one understands the concept of this patented FMS Technology system, together with the Cytyc Technology, one realizes that if a component is affected by either FMS or Cytyc Technologies, then it becomes a disposable, if it's part of this unit. It doesn't have to look like a filter. It doesn't have to look like a cylinder. It can look like a collection device or the other things as well.

Exh. 6, Hearing Day 2 at 270. Apparently, the Panel found Mr. Goldscheider to be credible because it quoted him with approval. *See* Partial Final Award at 2.

Moreover, the License Agreement recites the parties' intent to include all technology used for preparing slides, not just the filter cylinders, in the royalty base:

> DEKA wishes to license to Cytyc the right to utilize FMS Technology to facilitate the preparation of slides . . . Cytyc is willing to limit the use of both FMS Technology and Cytyc Technology to the preparation of slides

Exh. 3, License Agreement at "Recitals" (emphasis added).

DEKA developed not just a processor and filter cylinder, but also "a method . . . for the preparation of slides." *Id.* (emphasis added). The parties thus intended that DEKA would be compensated for its technology, including the method, which employs all disposables. The Panel found that intent "reflected in the parties' agreement." Partial Final Award at 2.

Finally, the stated definition of "Product Disposables" "presently includes Cytyc's 'TransCyt Filters.'" License Agreement at § 1.01(g) (emphasis added). The word "presently" shows that the parties anticipated that Cytyc might supply additional disposables not yet

finalized--*i.e.* "similar disposables"--and that they should be included in the royalty base. The word "includes," as the Panel held, is a broad term that suggests that other items are included as well. Partial Final Award at 2. The definition does not state, for example, "Product Disposables is the filter cylinder." Rather, the term "includes" the filter cylinder and other devices as well. Thus, the parties listed what they then "presently" understood Cytyc would be supplying and left room for not yet specified "similar disposables" and "Improvements," which are expressly part of the royalty base. DEKA submitted evidence, such as documents Cytyc submitted for FDA approval of the ThinPrep system (which Cytyc withheld from DEKA until after the hearing started), showing that, when the agreement was being negotiated, Cytyc did not yet know which of the four disposables it would eventually sell. For example, Cytyc was not then considering selling a slide and collection device. Thus, by choosing the word "presently," the parties left room for any other disposables that Cytyc might include in the future. *See* **Exh. 16,** DEKA's Post-Hearing Reply Brief at 2-3 (detailing the evidence on similar disposables).[5]

B. The Parties' Dealings Confirm Their Intent to Include All Disposables

As the Panel found, the "evidence shows that the parties never intended that royalties would be paid on parts of the Kit rather than the Kit as a whole." Partial Final Award at 2-3. The Panel likely gleaned the parties' intent directly from the words of the License Agreement itself, as shown above, and thus had little need to delve into the extrinsic evidence. To the extent that the Panel was inclined to consider extrinsic evidence, however, it had ample support in the

[5] Cytyc relies on a canon of construction, "*expressio unius est exclusio alterius*," for the proposition that other disposables are excluded from the agreement. That canon, however, "is only a guide, whose fallibility can be shown by contrary indications." *United States v. Vonn*, 535 U.S. 55, 65 (2002). Here, the term "Product Disposables" contains such "contrary indications" because it includes not just a filter cylinder but also any "similar disposable," which broadly refers to any other disposable needed to make a slide.

record for its holding that the royalty was meant to apply to all disposables sold by Cytyc.

For example, in January 1992, after Cytyc had begun selling the ThinPrep system but still before the parties finalized the formal agreement, Cytyc sought to pay DEKA the royalties it deserved. Accordingly, Cytyc's founder, Mr. Lapidus, wrote to DEKA that he would pay royalties based on the parties "handshake understanding" that the royalty applied to all "ThinPrep sales," not merely to the filter cylinders:

> I'm enclosing a royalty check based on ThinPrep sales for 1991. . . . I'm sending you this check even though we have not yet consummated the royalty agreement. I would prefer to pay you your royalty under a signed agreement, but am content doing it on the basis of our handshake understanding.

Exh. 17 (emphasis added).

Significantly, the royalty schedule accompanying Mr. Lapidus's letter shows that Cytyc paid royalties on "Disposables (Total)." *Id.* at 20407. This royalty schedule does not show that Cytyc limited the royalty to just a portion of the ThinPrep system. Indeed, the schedule confirms that the royalty applied to "Total" disposables. Cytyc was selling the preservative solution then (*see* **Exh. 8**, Lapidus depo. at 75), so it follows that this royalty was paid on the solution as well. Even Cytyc's CEO, Mr. Sullivan, said that he had no basis for denying that this 1992 royalty included the solution. *See* **Exh. 7,** Hearing Day 3 at 92 and 95. In other words, the royalty base included "Total" sales of all disposables used to make a slide. And that payment was based on the parties' "handshake understanding,"

The parties' negotiations closest in time to the final agreement also demonstrate that the parties revised their early positions and decided to include all disposables in the royalty base. For example, in October 1991, DEKA's attorney, Stephen Hazard, wrote to Lapidus with the concern that the proprietary products could be bundled with items unrelated to making a slide and that, therefore, "it may be difficult to determine how the different pieces of the unit are

priced" for purposes of calculating the royalty. **Exh. 18**, Letter of October 14, 1991. Attorney Hazard thus suggested an "Agreed Sales Price" concept or an alternative "percentage of total disposable sales" approach for determining the royalties. *Id.* Cytyc, however, never adopted this approach and never suggested alternative ways to solve Hazard's concern. The final agreement certainly does not specify any method for apportioning royalties. Indeed, Lapidus said that he would never have agreed to Hazard's suggested approach because it would be "unfair to Cytyc or unfair to Dean." **Exh. 8**, Lapidus depo. at 73 (emphasis added).

The parties eventually decided that the royalties would be paid on total sales because the next drafts that the parties exchanged, and indeed the final agreement itself, do not mention any method to limit royalties to the filter cylinders. Moreover, Cytyc gave up on its proposal from years earlier to exclude vials of fluid from the royalty base. Cytyc did not insist on an express exclusion of the vials in the final agreement. Accordingly, such an express exclusion may not be re-inserted into the final agreement. *See, e.g., Accusoft Corp. v. Palo*, 237 F.3d 31, 42 (1st Cir. 2001) (defendant took risk that its unspoken understanding of agreement was incorrect); *M&M Transp. Co. v. Schuster Express, Inc.*, 13 B.R. 861, 872 (Bankr. S.D.N.Y. 1981) (defendant bore risk because it knew of a contingency and could have crafted a provision to address it).

III. THE PANEL DID NOT MANIFESTLY DISREGARD THE LAW

The First Circuit recognizes two instances in which an award is subject to review: (1) when the award is contrary to the plain wording of the agreement and (2) when it is clear from the record that the arbitrator recognized the applicable law but then ignored it. *Advest, Inc. v. McCarthy*, 914 F.2d 6, 9 (1st Cir. 1990) (affirming denial of motion to vacate). As seen above, the award is not contrary to the plain wording of the agreement. The second category is often labeled "manifest disregard" of the law. This "manifest disregard" standard can be met only

when the applicant shows "that the arbitrators knew the law and expressly disregarded it." *Id.* at 10 (emphasis added). Here, there is no express statement in either award that the Panel recognized the authority of a particular provision but would ignore it anyway. [6]

Although Cytyc claims to argue that the Panel ignored the law, what it is really arguing is that the Panel did not expressly credit all of the extrinsic evidence that Cytyc claimed helped its case. Indeed, Cytyc concedes that "vacatur would likely not be appropriate had the panel considered but rejected this extrinsic evidence of the meaning of the Agreement, *e.g.*, by pointing to countervailing extrinsic evidence or overriding contractual language." Cytyc's Memorandum in Support of Application to Vacate Arbitration Award at 12.

There are three problems with Cytyc's argument, however. First, the Panel was not required to expressly accept or reject Cytyc's evidence. Second, the Panel relied on "overriding contractual language." Third, the Panel followed the governing contract law--to the extent it was even obligated to do so. Thus, by Cytyc's own reasoning, vacatur is not appropriate here. [7]

A. The Panel Considered All of the Evidence

Cytyc merely assumes that the Panel failed to consider the extrinsic evidence. But just because the Panel did not expressly cite specific evidence does not mean that the Panel failed to consider it. *See, e.g., Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1150 (Fed. Cir. 1983) ("That

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[6] *Advest* does not create additional categories for vacating awards, such as "arbitrary and capricious" or "unfounded in reason and fact," as Cytyc contends. The First Circuit declined to recognize these additional grounds. *Advest* , 914 F.2d at 9, fn.6.

[7] Cytyc relies on *McCarthy v. Citigroup Global Markets, Inc.*, as an example of an award vacated for manifest disregard of applicable law. But in that case, the arbitrators expressly stated that they did not consider the applicable law, considering it to be "irrelevant." *McCarthy*, 2005 U.S. Dist. LEXIS 2901 at *7 and 9. But in this case, there is no such express statement in either award showing that the Panel recognized a particular law, labeled it "irrelevant," and then ignored it. Cytyc also improperly relies on the district court's opinion in *Bull HN Info. Sys.* (at 983 F. Supp. 284) *See* Cytyc's brief at 17. The First Circuit ultimately reversed that opinion.

[the] testimony was not mentioned [in the opinion under review] does not mean that it was not considered"); *see also Davis Assocs. v. Laurion*, 367 A.2d 579, 580 (N.H. 1976) (reviewing court assumes that arbitrators considered all evidence submitted to them).

No law or rule required the Panel to expressly credit every piece of evidence and every argument that the parties submitted. Although Cytyc belittles the Partial Final Award as "terse," Cytyc's Memorandum at 8, that is no cause for complaint. As the First Circuit has observed, the "arbitrators need not state any reason for their decision . . . and if they choose to say anything, are often remarkably terse." *Bull HN Info. Sys.*, 229 F.3d at 331 n.7 (emphasis added); *see also Raytheon Co. v. Automated Bus. Sys., Inc.*, 882 F.2d 6, 8 (1st Cir. 1989) (court may not set aside an award merely because the arbitrators omitted formal findings of fact); *Davis Assocs.*, 367 A.2d at 580 ("Arbitrators are not required to detail the process by which they reach their result").

B. The Panel Relied on "Overriding Contractual Language"

As seen above, the Panel hinged the award on "overriding contractual language"--namely, the definition of "Product Disposables." Nothing in the awards suggests that the Panel strayed from the contract or ignored its words. The Panel did not base the award on some arbitrary "brand of industrial justice," as Cytyc contends. Indeed, in rejecting DEKA's equitable and tort claims (breach of duty of good faith, breach of fiduciary duty, and unfair or deceptive trade practices), the Panel emphasized that "[w]hatever rights and duties the parties owe to each other are strictly contractual in nature . . ." Partial Final Award at 3 (emphasis added). Thus, the Panel expressly relied on the contract, not on purely equitable factors, as Cytyc contends.

Although Cytyc wanted the Panel to focus on "Product Disposables," Cytyc ignored that term and instead touted parol evidence. For example, Cytyc relied on a May 1990 letter between Kamen and Lapidus stating that "Vials filled with collection medium are explicitly excluded

from this Agreement." **Exh. 19**. That letter is dated three years before the agreement was finalized. In the intervening years, the parties revised their expectations. Based on a "handshake understanding," Cytyc paid royalties on total disposables. **Exh. 17.** Because the Partial Final Award also uses the phrase "total disposables," the Panel apparently credited this evidence.

Moreover, the License Agreement contains a merger clause stating that the agreement "constitutes the entire understanding of the parties . . . and supersedes all prior understandings and writings relating thereto." **Exh. 3**, License Agreement at § 13.5 (emphasis added). The Panel was certainly aware of this "overriding contractual language." Indeed, the Panel understood full well the import of merger clauses and said so at the hearing **Exh. 5,** Hearing Day 1 at 261 ("We can probably give you a lecture on merger clauses").

Under New Hampshire law, a contract with a merger clause is complete, absent strong evidence to the contrary. Parol evidence cannot be used to add a term not present in--or deleted from earlier drafts of--the final contract. *See, e.g., Richey v. Leighton*, 632 A.2d 1215, 1216-17 (N.H. 1993). Cytyc offered no evidence that the agreement is incomplete. Thus, Cytyc cannot rely on parol evidence to add a discarded term--that vials are excluded--to the final agreement.[8]

C. The Panel Correctly Followed Governing Contract Law

Arbitrators are "not required to follow principles of contract law or judicial precedent." *United Food and Commercial Workers Int'l Union* 776 F.2d at 22. Thus, Cytyc's "manifest disregard" argument does not apply here. Even if the Panel were required to follow contract law (and the Panel consisted of three judges who, by training and education, were certainly inclined

[8] Even had the Panel based the award entirely on equity, that would not be enough to vacate it. *See* AAA Rule R-43(a) ("arbitrator may grant any remedy or relief that the arbitrator deems just and equitable"); *United Food and Commercial Workers Int'l Union,* 776 F.2d at 22 ("The arbitrator's decision must be simply in the realm of what a judge might decide").

to do so), the Panel was not required to follow the statutes on which Cytyc relies.

Specifically, Cytyc's contention that the Panel disregarded RSA § 382-A:2-208 and § 382-A:1-205 is flawed in two respects. First, these UCC provisions apply only to contracts for sales of goods. They do not apply to technology licenses like the one at issue. *See* RSA § 382-A:1-105(a) (definition of "goods" does not include "general intangibles"). *See also, e .g., In re SSE Int'l Corp.*, 198 B.R. 667, 670 (Bankr. W.D. Pa. 1996) ("Intellectual property, or rights to thoughts, ideas, and concepts protected by patent . . . are widely accepted as not constituting goods and, therefore, are not covered under [UCC Article 2]").

Second, even assuming that those UCC provisions apply, New Hampshire law also provides that the final wording of an agreement trumps extrinsic evidence. *See Appeal of Town of Durham*, 821 A.2d 1097, 1100 (N.H. 2003) ("Because the language of the CBA is clear . . . we need not look to the practices of the parties or other extrinsic evidence"); *Robbins v. Salem Radiology*, 764 A.2d 885, 887 (N.H. 2000) ("Absent ambiguity, however, the parties' intent will be determined from the plain meaning of the language used in the contract").

Even if the definition of "Product Disposables" were ambiguous and thus open to parol evidence, Cytyc cannot presume that the Panel would have favored Cytyc's arguments. As shown above, DEKA cited substantial "countervailing extrinsic evidence" that the Panel could equally have adopted--and likely did, given the outcome.

IV. CYTYC'S RED HERRINGS

Instead of focusing on the words of the License Agreement, as the Panel did, Cytyc relies on extraneous matters, such as its allegations that (a) DEKA somehow did not immediately notify Cytyc that it was entitled to a royalty on all disposables and (b) Mr. Duffy failed to retain old notes. These matters are red herrings that Cytyc raised, repeatedly, in the arbitration but

which ultimately failed to sway the Panel. Indeed, there is an inconsistency in Cytyc's argument. Cytyc claims that DEKA somehow acted questionably but then argues that the Panel based its decision on equity--*i.e.*, that Cytyc acted unfairly--which belies Cytyc's argument. In any event, None of Cytyc's allegations relate to the central dispute--the meaning of certain contract terms. While page limits do not permit DEKA to address all of these extraneous matters, suffice it to say that the Panel heard the allegations and was entitled to reject them. *See* AAA Rule R-31(b) (arbitrator has authority to "determine the admissibility, relevance, and materiality of the evidence offered"); *Gupta*, 274 F.3d at 3 (parties must accept arbitrator's view of the evidence).

In any event, DEKA refuted Cytyc's allegations. For example, DEKA's Mr. Duffy testified that, in early 2002, he told Cytyc that the royalty should apply to all disposables. *See* **Exh. 6**, Hearing Day 2 at 131 ("At the first meeting we had, yes, we had a discussion about what the License Agreement said and the fact it covers . . . similar disposables"). Mr. Duffy also testified that he did not "destroy" his notes and, in any event, his colleague, Mr. Grinnell, saved notes from the same meetings. *Id.* at 139-140 (Grinnell took notes); 145-146 (Duffy's custom was to dispose of his notes). But again, these distractions do not reveal the parties' intent, and the Panel was not required to accept Cytyc's contentions or even to consider them.

V. THE PANEL CORRECTLY CALCULATED PRE-JUDGMENT INTEREST

The parties agreed on use of the interest rats set forth in N.H. Rev. Stat. (RSA) § 336:1. The parties disagreed, however, on when to start the interest calculations--from the date of each breach of contract, as DEKA contended, or from the date DEKA filed the arbitration, as Cytyc contended. The Panel agreed with DEKA, and that decision is grounded in the law.

Specifically, the governing AAA rules provide that an award may include "interest at such rate and from such date as the arbitrator(s) may deem appropriate." Rule R-43(d)(i). Also,

under New Hampshire law, an arbitrator may award interest "for money wrongfully detained . . . from the time the money is due." *John A. Cookson Co. v. New Hampshire Ball Bearings, Inc.*, 787 A.2d 858, 867 (N.H. 2001) ("arbitrators may include interest in an award unless the parties have expressly provided otherwise in their contract or arbitration agreement") (citations omitted).

Cytyc improperly relies on New Hampshire's RSA 524:1-b for the proposition that prejudgment interest is calculated from the date the arbitration was filed. But that statute does not limit this Panel's discretion to award interest from the date of each breach. *See Major v. Acorn Investment Co.*, 588 A.2d 811, 812 (N.H. 1991) (holding that RSA 524:1-b expressly applies only to "civil proceedings," meaning court litigation, not arbitrations). Accordingly, the Panel was correct in awarding interest from the date of the breaches.

VI. THE PANEL STAYED WITHIN ITS DELEGATED AUTHORITY

The parties' arbitration clause (§ 12.1) broadly applies to "any dispute, controversy or claim arising out of or relating to this Agreement, or the breach thereof." The Panel was thus authorized to settle this royalty dispute, which at its core involved interpretation and application of the License Agreement. Indeed, the Panel made clear that the parties' relationship is governed by contractual rights. The Panel then proceeded to wrestle with the very contractual provision--"Product Disposables"--that Cytyc wanted construed. The whole gist of the decision is the Panel's focus on what "is reflected in the parties' agreement." Partial Final Award at 2.

Neither award mentions the "Entire Market Value Rule," but the Panel could have relied on it, if it so chose. DEKA argued that, in addition to the express contract wording, the Entire Market Value Rule would also require payment of royalties on total disposables, and cited cases applying the rule to contract cases. *See* **Exh. 15,** DEKA's Post-Hearing Brief at 15-20. Thus, to

the extent that the Panel relied on the Entire Market Value Rule--and there is no indication that it did--it would have been appropriate to do so.

VII. CYTYC MAY NOT DEDUCT COMMISSIONS

The Panel ruled that Cytyc may not deduct commissions from the royalties. The Panel correctly relied on the words of the agreement, which states that the commissions may be deducted only if they are "actually stated on a customer invoice by Cytyc or Cytyc's affiliates." License Agreement at § 1.01(e). If there were ever contract wording that is clear and in need of no further interpretation, this is it. The Panel found that "the only customer invoices in the record are devoid of any such statement of commissions." Final Award at 1. This Court must accept that finding of fact. *Wonderland Greyhound Park,* 274 F.3d at 36-37.

Cytyc cannot argue that it had no opportunity to address this issue. DEKA raised the issue in its initial brief on calculation of unpaid royalties, which was filed while the hearing was still open (the Panel officially closed the evidence later, by letter dated April 11, 2005). Cytyc submitted a reply brief addressing this issue, but admitted that it had no invoices actually stating commissions. Thus, the Panel correctly determined the issue. *See, e.g., Nationwide Mut. Ins. Co. v. First State Ins. Co.*, 213 F. Supp.2d 10, 19 (D. Mass. 2002) (arbitrators that accepted briefs and heard three days of testimony were not required to reopen discovery or hear more evidence).

VIII. DEKA IS ENTITLED TO ATTORNEYS' FEES

The Panel awarded DEKA $1 million "toward reimbursement of DEKA's legal fees and expenses in this arbitration proceeding." **Exh. 2**, Final Award at 2. The parties' arbitration clause (§ 12.1) grants the Panel "the right to assess the losing party with the legal fees and expenses of both parties." Thus, the Panel had the authority to award fees and costs.

That same contractual provision allows this Court to tax Cytyc with DEKA's additional legal fees and costs. Cytyc has based this appeal solely on speculation and assumptions as to what the Panel may or may not have considered and has overlooked the Panel's actual written decisions. Moreover, even in the face of the Panel's rebuke of Cytyc's method of paying royalties, Cytyc, without explanation, did not make any payment to DEKA for Q1 2005 (due on May 15th)--even though, during the arbitration, Cytyc continued to pay quarterly royalties under its former calculation methods. Thus, Cytyc should compensate DEKA for the expenses it was forced to incur due to Cytyc's refusal to abide by the award. *See, e.g, Courier-Citizen Co. v. Boston Electrotypers Union No. 11*, 702 F.2d 273, 282 (1st Cir. 1983) ("remedies include an award of attorneys' fees when a party 'without justification' contests an enforceable award").

CONCLUSION

For the reasons stated above, DEKA respectfully requests that this Court confirm the award, enter judgment on it, and deny Cytyc's application to vacate it. DEKA also requests that the Court order Cytyc to pay interest accrued since the issuance of the Final Award and tax Cytyc with DEKA's fees and costs.

DATED: May 19, 2005

DEKA PRODUCTS LIMITED PARTNERSHIP

/s/ Erik P. Belt

Lee Carl Bromberg, BBO # 058480
Erik Paul Belt, BBO # 558620
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EXHIBIT 1

AMERICAN ARBITRATION ASSOCIATION

DEKA PRODUCTS LIMITED PARTNERSHIP,

Claimant

v.

CYTYC CORPORATION,

Respondent

Case No. 11 Y 133 02624 03
Case Manager: Ms. Paula Dubois

PARTIAL FINAL AWARD

1. Royalty Base

On March 22, 1993 the parties to this arbitration entered into a License Agreement wherein DEKA (Claimant) licensed to Cytyc (Respondent) the right to utilize "FMS Technology" for the preparation of slides for medical and laboratory purposes, specifically for Pap smear tests, for which Cytyc would pay DEKA a royalty of one percent (1%) of net sales of "Products or Improvements."

The central issues in this arbitration are what is meant by "Products and Improvements" and how should a royalty "equal to one percent (1%) of the Net Sales" be calculated.

The parties were successful in developing a lucrative ThinPrep Pap Test, which is based on the ThinPrep System consisting of the processor and four disposables (the "Kit"): (1) the filter cylinder, (2) the vial of preservative solution, (3) the microscope slide, and (4) the collection device.

DEKA claims that royalty payments of one percent (1%) are due on the total net sales price of the four disposables, while Cytyc asserts that royalties are due only on the filter component and are to be determined by a "relative cost ratio" formula. By that formula Cytyc has determined the base on which to apply the one percent (1%) royalty by calculating the ratio of the filter cost to the total Kit cost and then multiplying net Kit sales by that ratio.

The evidence reveals that Cytyc's founder, Stan Lapidus, sought out his friend Dean Kamen, DEKA's founder, to solve a critical problem he confronted in developing a system to machine-read Pap smear slides. A way was needed to prepare a uniform, thin-layered slide specimen unobscured by clumps of mucus and blood. Kamen had patented the FMS (Fluid Management System) technology, which could be adapted for use in slide preparation. The two entered into a financial and work allocation arrangement to develop the ThinPrep slide preparation system. That system has proven highly successful, both technically and financially. The evidence establishes that the development of the ThinPrep system was a collaborative effort and that indeed the "key" component of that system was the FMS technology. Without the filter, the system would not work and would have no value.

As DEKA's technology licensing expert Robert Goldscheider testified:

> FMS Technology is a system; it is not a specific product. It is the operation of a system on certain components. In this particular situation the components are the four units that were approved by the FDA: the filter, the collection device, the vial and the slide. And it is the operation of the FMS Technology, in conjunction with these units, which Mr. Sullivan tells us in his deposition are worthless by themselves, but when put together and governed by this patented system, the FMS Technology, it becomes enormously valuable.

The accuracy of this assessment is reflected in the parties' agreement. The License Agreement defines "Products" to include "Product Hardware" and "Product Disposables." Product Disposables means any filter cylinder or similar disposable utilizing Cytyc and/or FMS Technology. The four disposables are systematically integrated by design and function in order to work and in order to be patentable.

The phrase "or similar disposable provided such disposable utilizes the Cytyc Technology, the FMS Technology or both" cannot be read to be restricted to only the filter. The very next sentence, which reads "Product Disposable presently includes (emphasis supplied) Cytyc's 'TransCyt Filters'," must mean that the term "Disposables" includes the other disposables in the Kit and any improvements or modifications.

Furthermore, we find that Cytyc's proposed formula for determining royalties is not only contrary to the agreement, but makes it difficult for the parties to fairly assess the value of each part of the Kit. Indeed the parts, if they could be sold separately, would have little value as it is the entire Kit that is approved for use, and the Kit works as a unit. The

evidence shows that the parties never intended that royalties would be paid on parts of the Kit rather that the Kit as a whole. Cytyc's view of royalty payment could lead to its benefiting by its fixing costs of the components in an arbitrary or unreasonable manner, or, as alleged by DEKA, by DEKA itself making cost-saving improvements on its filter, or by Cytyc's outsourcing the manufacture of the filter. We find that the evidence establishes that royalties of one percent (1%) are due on the net sales of total disposables.

2. **Defenses: Statute of Limitations, Laches, Estoppel, and Waiver**

We find that DEKA's claim is not barred by laches, estoppel or waiver, but we do find that under the applicable New Hampshire statute of limitations a contract claim must be commenced within three years of when it arose and that this three-year statute applies to DEKA's royalty claims. Therefore, DEKA may not receive any unpaid royalties that were due prior to November 17, 2000, three years prior to the date it filed its Demand in these proceedings. DEKA cannot avoid the bar of the statute of limitations because, in the exercise of reasonable diligence, DEKA "could" or "should" have discovered Cytyc's method of calculating royalties well before November 17, 2000.

3. **Other DEKA Claims**

We find that DEKA has failed to establish that Cytyc acted irrationally or in a secretive manner in its calculation of royalties. We therefore dismiss DEKA's claim for breach of implied covenant of good faith and fair dealing.

We dismiss DEKA's claim for deceptive trade practices as DEKA's claim is not based on deceptive or immoral acts.

The relationship between DEKA and Cytyc was at arms length, was an ordinary contractual relationship without any fiduciary duties, and therefore DEKA's claim of breach of fiduciary duty is also dismissed.

Whatever rights and duties the parties owe to each other are strictly contractual in nature and any claims asserted by DEKA are subsumed under its demand for royalty payments under the contract. In this context and in the face of the above rulings, we find no basis to award DEKA treble damages and that demand is dismissed.

4. **Cytyc's Claim of Termination and DEKA's Request for Injunction**

This panel has previously ruled that the license agreement has not been terminated and we adhere to that decision. We deny DEKA's request for injunctive relief as

unnecessary in light of our decision. The panel finds that the contractual relationship between the parties continues.

5. **Cost of KPMG Audit**

We find that by the terms of Section 3.03 of the License Agreement Cytyc is obligated to reimburse DEKA for the cost of the audit conducted by KMPG for the period 1996 through 2002. That audit disclosed "an underpayment of Cytyc's royalty obligations" under the License Agreement well in excess of $10,000 for the 1996-2002 period "which [was] subject to the audit." Cytyc shall reimburse DEKA for its costs of the KMPG audit in the amount of $155,758.00 within 30 days of the date of this Partial Final Award.

6. **Calculation of Unpaid Royalties**

The panel, however, does not find it possible on the record before us to determine accurately the royalty payments remaining due to DEKA from November 17, 2000 forward and we therefore order the parties to submit and exchange initial royalty calculations, including the calculation of interest, limited to fifteen (15) pages within fifteen (15) days from the date of this Partial Final Award with reply calculations to be submitted and exchanged within twenty-five (25) days of that date. The royalty calculations should cover a period through the end of the most recent quarter. Any evidentiary material outside the existing record should be presented by affidavit.

7. **Reservation of Final Decision**

Subject to the above submissions, the panel reserves decision on the amount of the award of unpaid royalties with interest due to DEKA, on attorney fees and on the costs of arbitration and any other costs.

SO ORDERED:

DATED: 3/7/05

B. Leo Milonas
Arbitrator

Vincent L. McKusick
Arbitrator

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EXHIBIT 2

AMERICAN ARBITRATION ASSOCIATION
Commercial Arbitration Tribunal

In the Matter of the Arbitration between

Re: 11 133 Y 02624 03
DEKA Products Limited Partnership ("DEKA")
and
Cytyc Corporation ("Cytyc")

FINAL AWARD OF ARBITRATORS

WE, THE UNDERSIGNED ARBITRATORS, having been designated in accordance with the arbitration agreement entered into by the above-named parties and dated March 22, 1993, and having been duly sworn, and having duly heard the proofs and allegations of the Parties, and having previously rendered a Partial Final Award dated March 7, 2005 and Claimant having made a motion to amend its claim and the Arbitrators having agreed to consider same do hereby, AWARD, as follows:

1. Panel's Earlier Decision. The Partial Final Award dated March 7, 2005, is incorporated herein and made a part hereof.

2. Unpaid Royalties and Interest. DEKA is awarded against Cytyc judgments in the amount of Seven Million Five Hundred Twenty Four Thousand One Hundred Sixty Eight Dollars and Zero Cents ($7,524,168.00), representing unpaid royalties that became due and payable during the period from November 17, 2000 through the end of 2004, and in the amount of Five Hundred Sixty Three Thousand Six Hundred Forty Five Dollars and Zero Cents ($563,645.00), representing interest on those unpaid royalties. Except as expressly noted below, the Panel has found persuasive the royalty and interest calculations set forth in the sworn declaration dated March 25, 2005, of DEKA's expert witness, Christopher C. Barry.

Commissions. In the determination of the base for royalties due under the License Agreement, *i.e.*, "net sales," section 1.01(e) plainly provides that commissions may be deducted to determine net sales only if those commissions are "actually stated on a customer invoice." The only customer invoices in the record are devoid of any such statement of commissions.

FirstCyte Products and Imager "Upcharge". Excluded from the Panel's award is any royalty on Cytyc's FirstCyte products or on the so-called "upcharge" that Cytyc has added to the ThinPrep Kit to serve

as a per-test user charge for the associated Imager. Claimant DEKA has failed to carry its burden of proof on those claims for the period covered by this arbitration proceeding.

"Reagent Rental". The Panel's award includes $24,436.00 in royalties and interest arising from Cytyc's "Reagent Rental" program – an alternative way of selling the ThinPrep System by giving the processor away for free or at a substantial discount and receiving income from the sale of disposables. Cytyc's Rebuttal Submission on Royalties raises no objection to DEKA's claim of a royalty on "Reagent Rental" that DEKA had asserted in its earlier submission on royalties and that DEKA's expert witness Barry had included in his earlier sworn declaration.

Interest. Commercial Arbitration Rule 43(d)(1) gives the Panel discretion to award "interest at such rate and from such date as the arbitrators may deem appropriate." The parties have agreed on the use of the applicable New Hampshire interest rate schedule. Equity requires that interest start to run on each quarterly royalty payment on the date it became due.

3. Legal Fees and Expenses. DEKA is awarded against Cytyc a judgment in the amount of One Million Dollars and Zero Cents ($1,000,000.00) toward reimbursement of DEKA's legal fees and expenses in this arbitration proceeding, including expert fees and expenses and payments to the American Arbitration Association.

Section 12.1 of the License Agreement provides that the Panel has "the right to assess the losing party with the legal fees and expenses of both parties." This award reduces the legal fees and costs that DEKA has actually incurred, to reflect the fact that Cytyc is not "the losing party" on DEKA's claim for unpaid royalties that became due prior to November 17, 2000.

4. Payment Date. Cytyc shall make the payments to DEKA required by paragraphs 2 and 3 within 30 days of the date of this Final Award.

In the Matter of the Arbitration between

Re: 11 133 Y 02624 03
DEKA Products Limited Partnership ("Claimant")
and
Cytyc Corporation ("Respondent")

The administrative fees of the American Arbitration Association ("the Association") totaling $18,950.00 and the compensation and expenses of the arbitrators totaling $112,120.02 shall be borne by Cytyc. Therefore, Cyctc shall reimburse DEKA as outlined in Paragraph 3 above. Cytyc shall pay to the Association the sum of $19,560.02, representing amounts still due the Association. This amount reflects all payments made to date.

This Award is in full settlement of all claims and counterclaims submitted to this Arbitration. All claims not expressly granted herein are hereby, denied.

This Award may be executed in any number of counterparts, each of which shall be deemed an original, and all of which shall constitute together one and the same instrument.

Date

E. Leo Milonas

4/25/05
Date

Vincent L. McKusick

I, E. Leo Milonas, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument which is my Award.

Date

E. Leo Milonas

I, Vincent L. McKusick, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument which is my Award.

4/25/05
Date

Vincent L. McKusick

In the Matter of the Arbitration between

Re: 11 133 Y 02624 03
DEKA Products Limited Partnership ("Claimant")
and
Cytyc Corporation ("Respondent")

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4/25/05
Date

E. Leo Milonas

Date

Vincent L. McKusick

I, E. Leo Milonas, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument which is my Award.

4/25/05
Date

E. Leo Milonas

EXHIBIT 3

CYTYC/DEKA
LICENSE AGREEMENT

This Agreement is made this 22nd day of March, 1993, between DEKA Products Limited Partnership ("DEKA"), a limited partnership with its principal place of business in Manchester, New Hampshire, and Cytyc Corporation ("Cytyc"), a Delaware corporation with its principal place of business in Marlborough, Massachusetts.

RECITALS

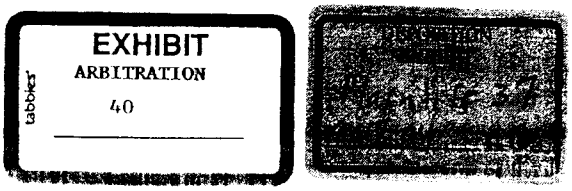
At Cytyc's request, Deka Research & Development Corp. ("R&D"), general partner of DEKA, has assisted Cytyc in the development of a method and apparatus for the controlled instrumented processing of particles with a filter device used for the preparation of slides for medical and laboratory purposes (the "Product Hardware", as defined below). The method and apparatus utilizes pre-existing fluid pumping and control technology owned and developed by DEKA (the "FMS Technology" as defined below) together with certain newly developed technology which provides an improved method and apparatus for quantizing cells and other particles carried in a fluid medium (the "Cytyc Technology" as defined below).

DEKA wishes to license to Cytyc the right to utilize FMS Technology to facilitate the preparation of slides for medical and laboratory purposes. Cytyc is willing to limit the use of both FMS Technology and Cytyc Technology to the preparation of slides for medical and laboratory purposes, and to license back to DEKA the right to use Cytyc Technology for all other purposes, so as to eliminate any possible conflict with other research and development work conducted by DEKA for its own account or for the benefit of others.

NOW, THEREFORE, in consideration of their mutual promises, Cytyc and DEKA agree to the terms and conditions set forth below:

ARTICLE ONE
DEFINITIONS

1.01 Definitions. The following terms wherever used in this Agreement shall have the meanings set forth below:



(a) Cytyc Technology. "Cytyc Technology" shall mean the technology reflected in Patent Application CYM-001, Serial Number 487,637 filed on March 2, 1990, entitled "Method and Apparatus for Controlled Instrumentation of Particles with a Filter Device" together with all technology incorporated in the Products, and together with patents, patent applications and divisions, continuations, continuations-in-part, reexaminations and reissues of any of the foregoing, and all inventions, drawings, prototypes, schematics, trade secrets, know-how, formulae, compositions of matter, designs and intellectual property rights existing that embody or are embodied by, in whole or in part, any of such technology or that pertain to it, including all foreign counterparts to the above, but in all cases excluding and subject to FMS Technology.

(b) Field of Use. "Field of Use" shall mean the field of preparing and examining slides for medical or laboratory purposes.

(c) FMS Technology. "FMS Technology" shall mean technology reflected in those patents and patent applications listed in Exhibit A attached hereto, now owned by DEKA or in which DEKA has rights, together with patents, patent applications and divisions, continuations, continuations-in-part, reexaminations and reissues of any of the foregoing, and all inventions, drawings, prototypes, schematics, trade secrets, know-how, formulae, compositions of matter, designs and other intellectual property rights existing, including all foreign counterparts to any of the above, which incorporate the concepts of such patents owned or controlled by DEKA, which issue or have issued in any jurisdiction in the world upon patent applications which correspond with any of such applications or patents or any divisions, continuation-in-whole or continuation-in-part thereof, and further includes all inventions, drawings, prototypes, schematics, trade secrets, know-how, formulae, software, compositions of matter, designs and intellectual property rights existing, developed by DEKA and included within Products.

(d) Improvements. "Improvements" shall mean any alteration of the Products made by Cytyc that allows the Products to perform the same or a substantially similar purpose as the Products in a better, more useful or more economical way, or any modification of the Products which permits a better, more useful or more economical means of manufacture of the Products.

(e) Net Sales. "Net Sales" shall mean the gross sales price, lease proceeds, royalty and licensing fees of Products or Improvements sold, leased or licensed to unrelated customers, less all applicable commissions, discounts and rebates, freight charges and returns and allowances, all if and to the extent allowed in the ordinary course of business and actually stated on a customer invoice by Cytyc or Cytyc's affiliates.

(f) Person. "Person" shall mean any individual, corporation, association, partnership, joint venture, trust, entity or organization.

(g) Product Disposables. "Product Disposables" shall mean any filter cylinder or similar disposable provided such disposable utilizes the Cytyc Technology, the FMS Technology or both. Product Disposable presently includes Cytyc's "TransCyt Filters".

(h) Product Hardware. "Product Hardware" shall mean a physical device for the controlled instrumented processing of particles for the preparation of slides provided such device utilizes the Cytyc Technology, the FMS Technology or both. Product Hardware presently includes Cytyc's "ThinPrep Processor".

(i) Products. "Products" shall mean Product Disposables and Product Hardware.

(j) Term. "Term" shall mean the term of this agreement as contemplated by Article Four hereof.

1.02 General. The terms defined in this Article One shall include the plural, as well as singular.

ARTICLE TWO
LICENSE

2.01 License of FMS Technology. Upon the terms and subject to the conditions set forth herin, DEKA hereby grants to Cytyc, and Cytyc herby accepts, an exclusive, world-wide license to utilize FMS Technology in the Field of Use for the Term (the "FMS License").

2.02 LICENSE OF CYTYC TECHNOLOGY. Cytyc shall have the perpetual, world-wide right to utilize Cytyc Technology in the Field of Use. Upon the terms and subject to the foregoing and the conditions hereof, Cytyc herby grants, and DEKA hereby accepts, the exclusive, world-wide, royalty free license to utilize Cytyc Technology in any and all areas outside the Field of Use (the "Cytyc License").

ARTICLE THREE
ROYALTY

3.01 Royalty. As consideration for the license of FMS Technology during the Term, Cytyc agrees to pay DEKA a royalty equal to One Percent (1%) of the Net Sales of Products or Improvements.

3.02 Payment. Within forty-five (45) days after the last day of each calendar quarter, Cytyc shall provide DEKA with a written statement prepared for the calendar quarter period just ended providing a single figure for Net Sales for such calendar quarter and a calculation of royalties owed. Payment of the royalty due for the applicable calendar quarter shall accompany the statement. The first statement and payment shall be due after the first calendar quarter period in which the Products are marketed and sold by Cytyc. Thereafter the report shall be made even if no royalty is due until the end of the Term. All royalties shall be payable in U.S. dollars and sales made in other currencies shall be translated into U.S. dollars at the exchange rate in effect at the end of each applicable calendar quarter.

3.03 Audit. DEKA shall have the right to retain an independent certified public accountant who will during normal business hours and upon reasonable notice (not less than fifteen (15) days), have access to and shall have the right to inspect and make extracts from such documents as may be necessary for the independent auditor to ascertain the accuracy of the single figure of Net Sales. An audit may be required once in any calendar year period during the Term and a final audit may be requested at any time within two (2) years following the last day of the Term. DEKA shall be responsible for all costs related to the audit, provided, in the event there has been an underpayment of Cytyc's royalty obligations hereunder in excess of $10,000 for the period which is subject to the audit, Cytyc shall reimburse DEKA for the cost of such audit.

ARTICLE FOUR
TERM AND TERMINATION

4.01 Term of FMS License. The effective date of this Agreement is January 1, 1990 and the term of this Agreement shall extend to the date of the expiration of all of the patents which are the basis of the FMS Technology.

4.02 Term of Cytyc License. The term of the Cytyc License shall be perpetual, unless otherwise terminated as provided herein. The purpose of the perpetual license of Cytyc Technology is to provide DEKA with the unlimited ability to utilize Cytyc Technology outside of the Field of Use without obligation of any kind to Cytyc.

4.03 Termination. The FMS License and Cytyc License only may be terminated as follows:

(a) Upon the mutual written consent of DEKA and Cytyc;

(b) by DEKA on written notice to Cytyc in the event that Cytyc purports to assign this Agreement other than in accordance with Section 13.1 hereof.

Termination shall not relieve Cytyc of its obligation to pay DEKA royalties earned to the date of termination as provided herein.

ARTICLE FIVE
DEKA RESPONSIBILITIES

5.01 Research and Development. DEKA has developed the Products, and Cytyc hereby acknowledges that the Products' concept and design are acceptable to Cytyc and that DEKA has fully performed all research and development and all other obligations to Cytyc. Any future research and development responsibilities will be undertaken pursuant to a separate agreement between DEKA and Cytyc, and the consideration for such services shall be separately determined.

5.02 FMS Technology. DEKA shall have the exclusive right and obligation, at its sole expense, to file, procure, maintain and enforce in the U.S. and such other countries as DEKA determines in its sole discretion, patents and patent applications pertaining to FMS Technology. Upon request, DEKA will provide Cytyc with a list of patents and patent applications, U.S. and foreign.

ARTICLE SIX
CYTYC OBLIGATIONS

6.01 Sales. Cytyc agrees to use all reasonable efforts consistent with Cytyc's overall business objectives to maximize the sales of Products or Improvements. DEKA acknowledges that the sale of Products or Improvements may be regulated by various governmental authorities, and that significant amounts of time may be necessary for regulatory compliance and/or to develop appropriate marketing, sales and manufacturing capabilities.

6.02 Cytyc Technology. Cytyc shall have the exclusive right and obligation, at its sole expense, to file, procure, maintain and enforce in the U.S. and such other countries as Cytyc determines in its sole discretion, patents and patent applications pertaining to Cytyc Technology. Upon request, Cytyc will provide DEKA with a list of patents and patent applications, U.S. and foreign.

ARTICLE SEVEN
CONFIDENTIALITY

7.01 Confidentiality. All technical data and know-how regardless of the form, pertaining or relating to, the FMS Technology and Cytyc Technology (whether tangible or intangible) including without limitation, each and every invention, trade secret, formula, process, routine, technique, concept, method or idea, and all software and related documentation in any state of development (including, but not limited to, source code, object code, flow charts, diagrams and other materials of any type whatsoever) and all rights of any kind in or to any of the foregoing (including without limitation copyrights, trade secret rights and patents) regardless of whether any or all of the foregoing constitutes copyrightable or patentable subject matter communicated to one party to the other under this Agreement shall be kept confidential. Each party shall take all reasonable steps to ensure that such confidential information does not pass negligently or otherwise into the hands of those unauthorized to receive it, and that such confidential information is not used for any purpose not authorized by this Agreement or other written agreement between the parties. Notwithstanding the foregoing, a party shall be relieved of the confidentiality obligations herein and not be prevented by this Agreement from utilizing any information received by it from any other party if:

(i) the information is or becomes generally available to the public through no fault of the receiving party;

(ii) the information is acquired in good faith in the future by the receiving party from a third party who is not under an obligation of confidence with respect to such information;

(iii) is required to be disclosed by any applicable judgment, order or decree of any court or governmental body or agency having jurisdiction or by any law, rule or regulation (including without limitation, any such securities law, rule or regulation relating to offerings of securities or periodic reporting requirements), provided that in connection with any such disclosure, the party disclosing such information shall give to the other party reasonable prior notice of the disclosure of any such information pursuant to this exception and shall obtain, to the extent possible, confidential treatment for such information by any authority requiring delivery of such information; or

(iv) the disclosure of such information is necessary for the commercial exploitation of any License granted

hereunder and the party to whom such information is being disclosed is advised of the confidential and proprietary nature of such information and agrees to be bound by appropriate confidentiality and non-disclosure agreements which prescribe the unauthorized disclosure or use of such information.

7.02 Survival After Termination. Notwithstanding any termination of this Agreement, the obligations of the parties with respect to the protection and nondisclosure of confidential information shall survive and continue to be enforceable.

ARTICLE EIGHT
INFRINGEMENT

8.01 (a) DEKA and Cytyc shall keep each other fully informed on a current basis, of the circumstances and details of any actual or potential infringements of FMS Technology and Cytyc Technology as utilized in the Products or Improvements of which they become aware. Cytyc, in the event of any actual or potential infringement of FMS Technology and/or Cytyc Technology as utilized in the Products or Improvements, shall have the right, but not the obligation, to institute suit against such actual or potential infringer and DEKA (at DEKA's expense) shall fully cooperate with Cytyc in any such action in the event the claimed infringement involves FMS Technology. In connection therewith, Cytyc may, at its sole election, require that DEKA join with Cytyc as a party to any infringement action brought by Cytyc hereunder. Cytyc shall bear all expenses associated with the foregoing. In addition, DEKA may, at its election, participate in any such action with counsel of its own choosing and at its own expense. Any recovery as a result of such action shall first be paid over to Cytyc and DEKA, pro rata in accordance with the reasonable expenses incurred by such parties (including, without limitation, reasonable fees and disbursements of counsel) up to the full aggregate amount of such expenses, and any additional recovery shall be allocated as hereafter provided. Cytyc and DEKA agree that in any suit including claims of FMS Technology and Cytyc Technology under this paragraph 8.01(a), they will request that a special verdict or other appropriate order or determination be made so as to specify those damages included in such ruling attributable to Cytyc and DEKA, respectively. In the event that no such ruling is made, Cytyc and DEKA shall negotiate in good faith to determine the manner in which such damages shall be allocated, and if Cytyc and DEKA fail to agree within thirty (30) days following the receipt of the proceeds of the recovery, the allocation shall be determined by arbitration as provided herein.

(b) DEKA agrees that Cytyc shall have the sole power to take legal action or other action (other than as contemplated by Sections 8.01(a) and 8.02 hereof) before any court or

governmental authority with respect to infringement or other protection of the FMS Technology and Cytyc Technology utilized in Products or Improvements. Notwithstanding the provisions of this subsection 8.01(b), if Cytyc does not institute suit against an infringer within one hundred twenty (120) days after notice thereof by DEKA to Cytyc of DEKA's desire to do so and if the circumstances and details of such infringement to the extent then known by DEKA, DEKA shall have the right to institute an action, with counsel of its own choosing, and may, at its sole election, require that Cytyc join with DEKA as a party to any such action. DEKA shall bear all expenses associated with actions undertaken pursuant to the foregoing sentence. Any recovery as a result of any action shall first be paid to Cytyc to the extent of all reasonable expenses incurred by Cytyc (including, without limitation, reasonable fees and disbursements of counsel) and the balance, if any, shall be paid over to DEKA.

(c) In the event Cytyc shall institute an action pursuant to Section 8.01(a) hereof and thereafter elects to abandon the same, Cytyc shall give timely notice to DEKA, which may, if it so desires, continue the litigation of such action in which event, for purposes of this Agreement, shall be deemed to have been instituted pursuant to paragraph 8.01(b) hereof.

8.02 With regard to any legal action instituted by Cytyc or DEKA pursuant to Section 8.01 above, the party instituting such action shall have the right to settle any disputes with third parties relating to the FMS Technology or Cytyc Technology as incorporated in Products or Improvements, provided, however, that if such settlement would result in the grant of rights to any Person that would diminish or dilute the License granted to DEKA hereunder or the rights of Cytyc in the FMS Technology, as the case may be, then no such settlement shall be agreed to without the prior consent of the party whose rights are so affected.

ARTICLE NINE
REPRESENTATIONS, WARRANTIES AND COVENANTS

9.01 Cytyc represents, warrants and covenants to DEKA as follows:

(a) Existence and Authority. Cytyc is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Cytyc is qualified to do business in Massachusetts as a foreign corporation.

(b) Authorization of Agreement. The execution, delivery and performance of this Agreement by Cytyc and the consummation of the transactions and agreements contemplated hereby have been duly and validly authorized by all necessary corporation action of Cytyc. This Agreement has been duly and validly executed and delivered by Cytyc and constitutes the valid

and binding obligation of Cytyc, enforceable in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium or other laws relating to creditors' rights generally, and subject to the availability of specific performance and injunctive and other forms of equitable relief.

(c) Effect of Agreement, Etc. The execution, delivery and performance of this Agreement by Cytyc and consummation by it of the transactions contemplated hereby, do not, with or without the giving of notice and the lapse of time, or both, (i) violate any provision of law, statute, rule, regulation or executive order to which Cytyc is subject; (ii) violate any judgment, order, writ or decree of any court to which Cytyc is subject; or (iii) result in the breach of or conflict with any term, covenant, condition or provisions of, result in or permit any other party to cause the modification or termination of, constitute a default under, or result in the creation or imposition of any lien, security interest, charge or encumbrance upon any of the Cytyc Technology pursuant to any partnership agreement, corporate charter document or, to the best knowledge of Cytyc, any commitment, contract or other agreement or instrument to which Cytyc is a party.

(d) Title to Cytyc Technology. The Cytyc Technology is owned by Cytyc free of all liens, claims and encumbrances, and the use of the Cytyc Technology and, to the best of Cytyc's knowledge, the grant of the DEKA License as contemplated hereby will not interfere with the rights of any third party, and no infringement of the Cytyc Technology is known to Cytyc. The patent (patent application) which is part of the Cytyc Technology has been maintained and has not been abandoned in any jurisdiction through nonuse or nonpayment of fees, annuities, taxes or the like and has not lapsed, expired or been opposed or cancelled or been the subject of a re-examination request in any jurisdiction.

9.02 DEKA represents and warrants to Cytyc as follows:

(a) Organization, Etc. DEKA is a limited partnership validly existing and in good standing under the laws of the State of New Hampshire.

(b) Authorization of Agreement. The execution, delivery and performance of this Agreement and any agreements contemplated hereby by DEKA have been duly and validly authorized by all necessary action, including all necessary corporate action of DEKA Research & Development Corporation, the sole general partner of DEKA. This Agreement has been duly and validly executed and delivered by DEKA and constitutes the valid and binding obligation of DEKA, enforceable in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium or other laws relating to creditors' rights generally,

and subject to the availability of specific performance and injunctive and other forms of equitable relief.

(c) Effect of Agreement, Etc. The execution, delivery and performance of this Agreement by DEKA and consummation by DEKA of the transactions contemplated hereby, will not, with or without the giving of notice and the lapse of time, or both, (i) violate any provision of law, statute, rule, regulation or executive order to which DEKA is subject; (ii) violate any judgment, order, writ or decree of any court to which DEKA is subject; or (iii) result in the breach or conflict with any term, covenant, condition or provision, result in or permit any other party to cause the modification or termination of, constitute a default under, or result in the creation or imposition of any lien, security interest, charge or encumbrance upon any of the FMS Technology pursuant to any partnership agreement, or to the best knowledge of DEKA, any commitment, contract or other agreement or instrument to which DEKA is a party.

(d) Title to FMS Technology. The FMS Technology within the Field of Use is owned by DEKA, free of all liens, claims and encumbrances, and, to the best of DEKA's knowledge, the use of the FMS Technology within the Field of Use and the grant of the license to utilize FMS Technology as contemplated hereby will not interfere with the rights of any third party, and no infringement of the FMS Technology within the Field of Use is known to DEKA. The patents which are part of the FMS Technology have been maintained and have not been abandoned in any jurisdiction through nonuse or nonpayment of fees, annuities, taxes or the like and have not lapsed, expired or been opposed or cancelled or been the subject of a re-examination request in any jurisdiction.

ARTICLE TEN
INSURANCE AND INDEMNIFICATION

10.1 During the term of this License Agreement, Cytyc shall, and shall cause each permitted or approved assignee or sublicensee to, at its or their own cost and expense, procure and maintain, product liability insurance against claims for personal injury and property damage caused by or occurring in connection the Products or Improvements, with limits of not less than $1 million per occurrence of loss or damage. Such policies of insurance shall name DEKA and/or its designees as an additional insured and shall provide that such policies shall not be cancelled except on not less than twenty (20) days prior written notice to DEKA.

10.2 Cytyc agrees to defend and indemnify and hold DEKA harmless against and from any and all liabilities, obligations, damages, penalties, claims, costs, charges, and expenses, including without limitation, reasonable attorneys' fees, which

may be imposed upon or incurred by or asserted against DEKA by reason of claims asserted by others, which arise out of the manufacture, use or sale of any Products or Improvements, which claims are not fully covered by insurance maintained by Cytyc as provided in Section 10.1.

ARTICLE ELEVEN
NOTICES

11.1 Notices. All notices or communications required or permitted by this Agreement shall be in writing and shall be sufficiently given if delivered or mailed by United States registered or certified mail, postage prepaid, return receipt requested, or delivered by an overnight delivery service, to the following addresses:

If to DEKA: Deka Research & Development Corp.,
General Partner
Deka Products Limited Partnership
340 Commercial Street
Manchester, New Hampshire 03101
Attention: President

If to Cytyc: Cytyc Corporation
237 Cedar Hill Street
Marlborough, MA 01752
Attention: President

Any party may change its address by written notice to the other party. All notices shall be deemed to have been given as of the date mailed or delivered to the overnight delivery service.

ARTICLE TWELVE
DISPUTES

12.1 Arbitration. Cytyc and DEKA agree that any dispute, controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be settled by arbitration to be conducted in Manchester, New Hampshire, in accordance with the Commercial Arbitration Rules of the American Arbitration Association, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. Cytyc and DEKA also agree that the arbitrator(s) shall have the right to assess the losing party with the legal fees and expenses of both parties.

12.2 Injunctive Relief. Notwithstanding Section 12.1, Cytyc and DEKA agree that in the event of a violation of, or a dispute arising under, the confidentiality provisions of Article Seven, a party may bring an action to obtain injunctive or other appropriate relief in any court having jurisdiction thereof.

ARTICLE THIRTEEN
MISCELLANEOUS

13.1 Assignment and Sublicenses. Cytyc may grant sublicenses hereunder, provided that any such sublicense contains confidentiality and infringement provisions substantially the same as those contained in ARTICLES SEVEN and EIGHT. Neither this Agreement nor any of the rights or obligations hereunder, including, without limitation, the licensed technology, may be assigned by either party without the prior written consent of the other party, which will not be unreasonably withheld; provided that Cytyc may assign its rights under this Agreement in connection with a sale of all or substantially all of its assets in a single transaction or series of related transactions to a single purchaser provided that such purchaser agrees in writing to be bound by all obligations of Cytyc hereunder.

13.2 Successors and Assigns. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their successors and permitted assigns.

13.3 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New Hampshire.

13.4 Headings. The headings contained in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement.

13.5 Entire Agreement. This Agreement constitutes the entire understanding of the parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating thereto. No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by the parties.

13.6 Counterparts. This Agreement may be executed in one or more counterparts, all of which taken together will constitute one and the same instrument.

13.7 Further Assurances. The parties agree to execute and deliver promptly to each other all such further instruments and documents as may reasonably be requested to carry out fully the intent, and to accomplish the purposes, of the transactions referred to herein.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date written above.

DEKA PRODUCTS LIMITED PARTNERSHIP

By: DEKA RESEARCH & DEVELOPMENT CORP., General Partner

By: _____
Dean Kamen, President

CYTYC CORPORATION

By: _____
Stanley Lapidus, President

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EXHIBIT A
SCHEDULE OF PATENTS

Invention	Product	Status			
Flow Control System Using Boyle's Law	FMS	Bar:		Filed:	03/04/86
		IR:	01/21/86	Ser No:	836,023
		Nov:	03/04/86	Issued:	10/18/88
		Clr:	03/04/86	Pat No:	4,778,451
		Pat:	Issued	Expires:	10/18/2005
Pressure Measurement Flow Control System	FMS	Bar:		Filed:	03/03/87
		IR:	11/21/86	Ser No:	021,289
		Nov:		Issued:	
		Clr:		Pat No:	
		Pat:	Abandoned	Expires:	
Boyle's Law - Dual Calibrators	FMS	Bar:		Filed:	
		IR:	11/24/86	Ser No:	
		Nov:		Issued:	
		Clr:		Pat No:	
		Pat:	Inactive	Expires:	
Boyle's Law - Porous Plug for Calibrator	FMS	Bar:		Filed:	
		IR:	11/24/86	Ser No:	
		Nov:		Issued:	
		Clr:		Pat No:	
		Pat:	Inactive	Expires:	
Boyle's Law - Motor Cam Drive Arrangement	FMS	Bar:		Filed:	
		IR:	11/24/86	Ser No:	
		Nov:		Issued:	
		Clr:		Pat No:	
		Pat:	Inactive	Expires:	
Infiltration Detection System Using Pressure Measurement	FMS	Bar:		Filed:	03/03/87
		IR:		Ser No:	021,294
		Nov:		Issued:	03/28/89
		Clr:		Pat No:	4,816,019
		Pat:	Issued	Expires:	03/28/2006

Invention	Product	Status	
Enhanced Pressure Measurement Flow Control System	FMS	Bar: IR: Nov: Clr: Pat: Pending	Filed: 09/01/88 Ser No: 88 908 607.0 Issued: Pat No: Expires:
Enhanced Pressure Measurement Flow Control System	FMS	Bar: IR: Nov: Clr: Pat: Pending	Filed: 09/01/88 Ser No: 63-507766 Issued: Pat No: Expires:
Enhanced Pressure Measurement Flow Control System	FMS	Bar: IR: Nov: Clr: Pat: Issued	Filed: 09/03/87 Ser No: 092,481 Issued: 05/02/89 Pat No: 4,826,482 Expires: 05/02/2006
Enhanced Pressure Measurement Flow Control System	FMS	Bar: 05/02/89 IR: 08/01/88 Nov: Clr: Pat: Issued	Filed: 05/01/89 Ser No: 345,387 Issued: 12/11/90 Pat No: 4,976,162 Expires: 12/11/2007

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Invention	Product	Status		
Infiltration Detection System Using Pressure Measurement	FMS	Bar: IR: Nov: Clr: Pat: Entered	Filed: Ser No: Issued: Pat No: Expires:	03/04/87 87/00514
Pressure Measurement Flow Control System	FMS	Bar: IR: Nov: Clr: Pat: Allowed	Filed: Ser No: Issued: Pat No: Expires:	03/04/87 87 902 007.1
Pressure Measurement Flow Control System	FMS	Bar: IR: Nov: Clr: Pat: Issued	Filed: Ser No: Issued: Pat No: Expires:	03/05/87 022,167 02/28/89 4,808,161 02/28/2006
Pressure Measurement Flow Control System	FMS	Bar: IR: Nov: Clr: Pat: Entered	Filed: Ser No: Issued: Pat No: Expires:	03/04/87 87/00515
Enhanced Pressure Measurement Flow Control System	FMS	Bar: IR: Nov: Clr: Pat: Allowed	Filed: Ser No: Issued: Pat No: Expires:	09/06/88 576,571

EXHIBIT 4

Welcome to the
United States Patent and Trademark Office
an Agency of the United States Department of Commerce

Search

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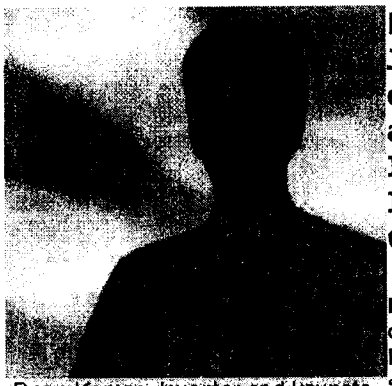
Top News ...



Dean Kamen, inventor and keynote speaker for this year's Independent Inventors Conference

Dean Kamen Joins Roster of Speakers at Independent Inventors Conference

Dean Kamen, one of the world's best known and most successful inventors, will be the keynote speaker at the opening session of the USPTO's annual **Independent Inventors Conference** in **Concord, N.H.** on **Friday, August 20**. Dean Kamen is President of DEKA Research and Development Corporation and Chairman of Segway LLC. As an inventor and physicist, Dean has dedicated his life to developing technologies that help people lead better lives. His inventions include a portable dialysis machine and the Segway™ Human Transporter. Dean is the recipient of the **2000 National Medal of Technology** and the **2002 Lemelson-MIT Prize for Invention and Innovation**.

The Independent Inventors Conference, co-sponsored by the **USPTO** and the **National Inventors Hall of Fame**, is designed for both novice and seasoned inventors. It will be held this year at the **Franklin Pierce Law Center August 20-21**. Top USPTO officials as well as intellectual property, marketing and licensing experts will make presentations. Topics to be covered at the conference include trademarks, copyrights, utility and design patents, provisional patent applications, invention promotion firms, electronic filing and on-line access, licensing and marketing. Attendees will have an opportunity for one-on-one sessions with the experts and there will also be plenty of time for inventors to network.

Space is limited and the **registration deadline** is **August 13**. The fee is $100 per person or $90 for seniors 55 and older. Register now online or by calling **(330) 849-6920**.

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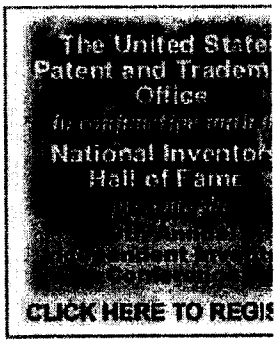

EXHIBIT 5

Volume I
Pages 1 to 264
Exhibits-See Index

AMERICAN ARBITRATION ASSOCIATION

Case No. 11 Y 133 02624 03

- -x

DEKA PRODUCTS LIMITED PARTNERSHIP,
Claimant,

vs.

CYTYC CORPORATION,
Respondent.

- -x

BEFORE: Hon. E. Leo Milonas, Chairman
Hon. Robert R. Merhige, Jr., Member
Hon. Vincent L. McKusick, Member

PRESENT:

Bromberg & Sunstein LLP
(by Lee Carl Bromberg, Esq., and
Erik Paul Belt, Esq.)
125 Summer Street, Boston, MA 02110-1618,
-and-
DEKA Research & Development Corporation
(by Maureen K. Toohey, Esq.)
340 Commercial Street, Manchester, NH
03101-1129, for the Claimant.

(Continued on Page 2)

PRESENT (Continued):

Howrey Simon Arnold & White, LLP
(by Matthew M. Wolf, Esq., Marc A. Cohn, Esq. and Nabina Sinha, Esq.)
1299 Pennsylvania Avenue, N.W.,
Washington, DC 20004-2402,
-and-
Cytyc Corporation (by Mark J. Casey, Esq.)
85 Swanson Road, Boxborough, MA 01719,
for the Respondent.

ALSO PRESENT: Dean Kamen
Brendan Duffy
Robert Goldscheider
Amy West
Iain Cockburn
Patrick Sullivan
Yvette Thomas
John Turnbull

-held at-
American Arbitration Association
133 Federal Street
Boston, Massachusetts
Monday, December 13, 2004
9:06 a.m.

(Anne H. Bohan, Registered Diplomate Reporter)

CHAIRMAN MILONAS: Right.

MR. BROMBERG: And in our view, a "disposable" means anything that's used to create this good slide as part of the FMS system. And that's, we think, what the definition says. And that's in the same exhibit, the same page, same section, except it's Subsection (g).

ARBITRATOR MERHIGE: Both parties knew the methods which were going to be used to determine the royalties, didn't they?

MR. BROMBERG: Yes, they did.

ARBITRATOR MERHIGE: And that method got changed?

MR. BROMBERG: That method got changed. It certainly got changed in '96, and then it got changed again, in our view, in '98, and then again in 2001.

ARBITRATOR MERHIGE: By the consent of both parties?

MR. BROMBERG: No. It was done unilaterally without notice.

ARBITRATOR MERHIGE: Without even telling them.

MR. BROMBERG: Without even telling them.

And I might add, Your Honor, without providing any description or explanation of how the royalties were being computed.

ARBITRATOR MERHIGE: I don't want to hit you with something. Just for a guy who knows little about it, that sounds unfair.

MR. BROMBERG: We believe it is unfair, Your Honor, and that's why we're here.

ARBITRATOR MERHIGE: It'd better be more than that.

MR. BROMBERG: I'm sorry?

ARBITRATOR MERHIGE: I said it'd better be more than that if you're going to enjoy your trip.

MR. BROMBERG: Yes, I agree, Your Honor.

It's our view that they implemented these methods to chisel away at the full amount of the royalty and have underpaid us and didn't tell us and didn't inform us. To this day, they have no explanation for this 20 percent rule. It was just arbitrarily adopted, never fixed, never changed, never made up.

And in 2001, Your Honors, they sent us a letter. Actually, what happened was, November of 2001, a royalty payment was missed. So people at

ARBITRATOR McKUSICK: Excuse me, Mr. Kamen.

A. I am an engineer and have a product development company in Manchester, New Hampshire.

Q. Can you describe your activities as an inventor to the Panel, sir.

A. I work mostly on medical products. I started my company when I was in high school and my older brother was in medical school, and I started building products for him, and I've been doing medical products for more than 30 years. On occasion, we've done a few projects that are not medical.

Q. Well, for example, can you describe for us your portable infusion pump for chemotherapy?

A. In the mid-1970s, I started building pumps that ended up about the size of a phone (indicating) that people would wear. The original reason actually to build them was for neonatology. My brother is an oncologist and a pharmacologist working on cancer in babies. They didn't at that time make equipment -- typical hospital equipment delivers fluid in large volumes.

In order to test some of his drug developments, he needed pumps that would work at a

very small scale. I built him pumps for that purpose and then realized that they were small enough that if I repackaged them, they could be used in a much larger market for adults; for instance, for delivering chemotherapy so that people getting cancer treatments could leave the hospital. And eventually the biggest market for wearable pumps was we made a product that size (indicating) for delivering insulin to diabetics. And that's a group of pump technology we developed.

Q. How about, did you do work on what's now called the HomeChoice Dialysis Machine?

A. After we finished the wearable pumps, we started a project to take dialysis equipment, which is very large, typically patients stay three nights a week living in a hospital, I mean literally living, watching your blood in an excretorial circuit float around in a kidney dialysis machine.

And we set out to build a device not much bigger than that (indicating) that could be made, A, small enough to put in somebody's home. More importantly, a technology that would be simple enough and safe enough to use in a home, that a cartridge could be put into the machine each night

by a patient treating themselves, the goal being you don't have to live in the hospital, you can treat yourself at home every night and live with end-stage renal failure.

And we did build a device called the HomeChoice which does that, and in the HomeChoice was some of the early FMS Technology. That was made, we started --

CHAIRMAN MILONAS: "FMS" being?

THE WITNESS: Fluid Management System.

A. To make a dialysis machine like that, simple and safe, we couldn't use pumps because they develop too much pressure. You have to worry about being able to not just deliver at a low pressure but read the pressure that's in the patient at all times. You have to be able to control the fluid and control valving. So we built a bunch of core technologies to make hardware and disposables, to pump fluids, to make a home dialysis machine, and we built the machine and the disposables.

CHAIRMAN MILONAS: Not that it's important to this case, but I'm just curious. Did you have a problem with air getting into the fluids?

THE WITNESS: Yes, you do and -- yes, you

do. And one of the -- there's a whole bunch of neat things that FMS does. One of the things it does is detect and eliminate air, which you can't do with a normal pump, which is one of the reasons, without an FMS machine, they wouldn't let patients go home and do dialysis at home. And we have separate patents within FMS called air detection and others on air elimination, which I'd be happy to show you, if you can find them.

MR. BROMBERG: They're somewhere in these exhibits in front of you, Judge.

CHAIRMAN MILONAS: I'm sure.

A. But that's a very critical problem and we solved that problem.

Q. What about IBOT, sir?

A. The IBOT is a product that just got FDA approval. If I were in an IBOT now, I could be sitting at a table. It has what looks like two wheels, front and back, that are very small compared to an ordinary wheelchair, but it's full of computers, gyroscopes, accelerometers, so that, A, if I happen to want to stand -- well, everybody is sitting -- but if everybody in this room decided to stand up and stand around, it would literally rotate

what we call the cluster up, so I would be standing nearly six feet tall, balanced on two wheels.

More importantly, if I took this device and went to a staircase, as it got to the stairs, when the front wheels hit the stairs, it wouldn't be able to move. The gyros would see all of this, the computers. Suffice it to say, there's a bunch of systems in there, it would literally rotate those clusters. So it's a wheelchair that while you're still sitting can walk up and down a flight of stairs, can go across... I think -- we're hoping it will do to wheelchairs what calculators did to adding machines. We spent about ten years developing the product; it's now approved.

Q. Who created the technology that's in that product, sir?

A. Me and our engineers at DEKA.

Q. Who obtained the FDA approval, Mr. Kamen?

A. Me and my engineers at DEKA.

Q. Is there a company that is now offering that product for sale?

A. Johnson & Johnson.

Q. Now, can you tell us what the Segway Human Transporter is, Mr. Kamen?

A. The Segway Human Transporter is a nonmedical device which happens to -- we took the same technology that we used to develop the J&J machine and just took away the seat and the cluster, because able-bodied people can walk. And to make it smaller or lighter and cheaper, we made a device with only two wheels that balances, using the same computers, the same algorithms, the same gyroscopes, as an IBOT, and it allows you to run around on only two wheels.

Q. Were you involved in the development of the Segway as well, sir?

A. Yes, we developed it.

Q. Now, Mr. Kamen, have you received any prizes and awards for your work as an inventor?

A. I received a lot, frankly. I received a couple of big ones. The National Medal of Technology in the year 2000 from the President of the United States for, among other things, the IBOT. Well, the citation said "Medical products worldwide healthcare," but I rode into the Oval Office on an IBOT. The Oval Office is not ADA compliant, you can't get in there with a wheelchair, but I went in there with an IBOT.

CHAIRMAN MILONAS: Off the record.

(Discussion off the record)

Q. How about the Lemelson-MIT prize; are you a recipient of that?

A. I was given the MIT-Lemelson prize I think in 2001 or 2002.

Q. What is that prize, sir?

A. I believe it is still the largest cash award; it's a major recognition. They like to say it's the Nobel Prize of engineering, because there is no Nobel Prize; they have it in physics and chemistry and medicine. But it's a half a million dollar prize from MIT-Lemelson to an inventor. They give out one a year.

Q. Did you receive the half a million dollar prize, sir?

A. I received the prize. I donated it to FIRST.

Q. What is FIRST? Can you tell the Panel what is FIRST, sir.

A. FIRST is a nonprofit organization that I started in around 1989 to try to convince kids, particularly women and minorities, that the probability they're going to make a career in the

NBA or in Hollywood is pretty slim. And this country has a very strange sense of priority, and I think in a free country, you get what you celebrate. I was trying to find a way to get kids to celebrate things besides Shaquille O'Neal and Britney Spears.

So I convinced at the time 20 some-odd companies -- big companies, General Electric, General Motors, Intel, United Technologies -- 20 some-odd companies to host a sports-like competition where each of these 20 companies would adopt a high school. We would give them the same duration of time as any sports season, event in a high school sports season. They'd build robots with these kids, they'd come, they'd celebrate, they'd bring the bands, they'd bring the cheerleaders, and off they go.

In the first year we did it, it got such a positive response of changing kids' attitudes about how successful and fun engineering and inventing is that it started growing. By the end of the fifth year, we couldn't do any events in New Hampshire, we were too big. We had a few hundred teams show up every year, a couple of hundred corporate sponsors.

For the next five years, from the fifth

year to the tenth year, we did our annual event on stage at Disney, at Epcot. In the 11th year, which is last year, it was so big we couldn't do it down there, we had to take over the Houston Astrodome. We had 500 companies, 500 high schools, and 4,000 middle schools had teams. And then last year we went to 800 corporate sponsors, 800 teams. The giant companies now have 20, 30, 40 teams in all of their plants around the country. And we took over, appropriately, the home of the 1996 Olympics, the Georgia Dome in Atlanta.

This year we have our kickoff January 8th. We will have over 1,000 corporate sponsors. We will be, again, in April in the Georgia Dome. We have over 5,000 middle schools, we have 500 international teams competing, and we have one of our -- we now have regional events in cities leading up to this. By the fifth year we started with two regionals; we grew from two to four to eight. We had 26 regional cities last year; this year we have 30 cities. And we have a regional happening in Israel in which we have 11 teams from Israel, three from Palestine and three from Jordan.

This is my only commercial for FIRST, but

it's important. It's a great program.

Q. Mr. Kamen, have you been contacted by the National Inventors Hall of Fame, sir?

A. Yes. In fact, a few weeks ago I was told that I will be inducted into the National Inventors Hall of Fame, I believe in February of 2005.

Q. Now let me turn your attention, sir, to your company, DEKA, which you already mentioned. Can you tell us when DEKA was founded.

A. Precisely I think in 1981 or '82. If it matters, I could get an exact answer.

Q. That's close enough.

A. '81 or '82.

Q. And what is the business of DEKA?

A. DEKA is in the business of designing, and in some cases limited production, of medical products.

Q. How many employees does DEKA have?

A. DEKA now has about 170 -- 170 employees.

Q. What is your role at DEKA, sir?

A. I'd like to say electrical, mechanical and other kinds of engineering and problem solving. Now I spend less and less time doing that, and my role is pretty much trying to make sure we're working on

Q. So can you think of another situation besides Cytyc in which you agreed to a 1 percent royalty, sir?

A. I think if you looked at our total royalties, there's no substantial amount of it that's coming in on stuff for which we had less than 4 percent.

Q. Now, sir, I wanted to turn to the project that you undertook for Cytyc. Can you take us back to when DEKA first undertook a project for Cytyc, sir.

A. I think it was in either 1988 or 1989.

Q. How did it start, Mr. Kamen?

A. I had gotten to know Stan Lapidus, I think at least a year or two before that, more because I think literally my parents were friends with a couple that were like parents to Stan and thought he was like boy wonder. And they were visiting one day and said to me, "You got to meet this guy." And I did. And they were right; he's a very smart guy.

And I went to his place, which literally, coincidentally, happened to be in one of the old mills in Manchester that was one building away from mine. And he had a company called Itran, and

Itran's business was computer vision. Today you might not think that's a big deal, but, what, 17, 18 years ago, it was a really big deal that this guy had.

Basically, the demonstration I first saw when I went in there was he had an ordinary -- I think it was a Sony home camera, connected to a little black and white T.V., a little cable connection, and the demonstration was that he was rolling ball bearings across a table. And a flash would go off, it would capture a frame, you'd look, and all the balls were in the races around the bearing. Then the next one would come by, and he'd take a snap, and the ball would be missing. So you'd see the silhouette.

And he took a mouse, and he would draw a circle around where something was missing; it didn't matter where it was in the frame. And the next time -- basically, he would teach you by just doing this. And he was basically saying, "Look, I built a system." He was using a computer to do what now would be called, I guess, nearest-neighbor analysis of the pixels to look for certain things. And then the computer would be taught that if it saw certain

kinds of nearest-neighbor things that it did or didn't like, it could identify them. So then he would turn on and roll a bunch of balls by and flash, and it would say: This is good; this is bad; this is good.

And of course, you could think of all the applications. And he was explaining to me that he had sold a bunch of these machines, I think to General Motors or Ford, somebody big in Detroit. And they were buying more and more of these systems because they could use it to inspect whether the needle valves were straight in the carburetor, how many balls were in a ball bearing. He was showing me all of his really neat capability to do visual assessment with this camera.

Q. Well, when you first did that visit, was the Cytyc project discussed at all?

A. No, no.

Q. This is a little earlier?

A. This is a little earlier. But I did leave there thinking, if he could measure these other things, I knew at the time we were working on the dialysis machine, I thought it could be really useful. When they make the needles and ports, the

inspection process, after they're all sharpened, it's a pretty expensive -- we all know medical stuff is expensive. I thought we could use his system, build a little fixture, spin needles around, look at it different ways and automate the process of literally telling whether they're sharp or not.

I went back, I saw him once or twice more. There's no way we had enough resolution to tell whether a needle was sharp with this thing; it was a few years away from that. But I got to play with it a little more, and we never did anything with the project. But he tried to help me.

Q. Did there come a time when he came to you with another project?

A. Yes.

Q. Can you describe that first meeting.

CHAIRMAN MILONAS: When was it?

THE WITNESS: The meeting I'm now going to discuss was I'm pretty sure in late '88 or '89.

A. How much time went by between what I just told you about, whether that was six months or a year or more, I don't really remember. I'm not sure it matters much, it's just that's what I knew about Stan, he was an expert on computer vision.

He comes to my office, and he says, "Dean, I sold or got" -- in some way he was pretty much "I'm done with Itran." I think he sold it to one of the giant companies. He said, "But I'm starting to do what you're doing, using my technology again." And he tells me that he can just take this camera and put it over the ocular of a microscope, look at a slide, and do his deal again.

This time he actually brought a camera with him, he had made it better and smaller, he had a little electronic box, brought the whole thing, and his demonstration was Cheerios and corn flakes. He did not bring cells with him, he brought Cheerios. He puts them down on the table, lights them up, takes about five minutes to draw pictures around, for instance, the Cheerios, even busted ones, because they're very dense and they have a high shadow, and then the corn flakes.

You're not even sure what the computer analysis was, but because they were maybe translucent, and he's looking at density, and maybe because of shape, he drew enough pictures around them that after he hit it a few more times, he could randomly put some Cheerios and some corn flakes

down, turn the thing on, and have the computer basically say, good, bad, good, bad. It was pretty impressive, especially back then.

He then says to me, "Dean, they do something like" -- I think he said like "50 million or 80 million, some huge number of Pap smears every year in the United States." He says, "With my system I am going to be able to automate the process" -- again, to his credit, I don't think he thought he could ever do it as well as a trained medical professional. But he said, "I don't have to be that good. I'll give them a lot of false-negatives. What I'm going to do is," he says, "the good news is, most of these 50 million slides that get read don't show squamous cells or cancer cells or precancer cells." They don't. I'm making this up, it's a very small number, but I'll say one in a thousand. It could be one in 700. It's a very small number.

He said -- so let's say it's one in a thousand -- "Somebody sits there and reads these things, takes 20 minutes apiece. A good technician might spend two weeks reading before they ever get to one that's really bad. And they're so used to

them being good, when they finally get to the bad one, they miss it."

So he's like all excited, and he says, "So I'm going to read them, and if there's any question at all that there's something that looks bad, because I'll train the machine, then I'll send it off. So even if nine out of 10 that I send on are bad, at least I eliminated" -- I mean, if he can get it down to nine out of 10, instead of them needing 1,000 and finding one bad one, they'll only have to read 10. He can get rid of 990, they'll do this, and it will be good. I said, "Great. That looks good to me."

He said, "I have one problem." I said, "What's the problem?" He says, "When they get these slides, a normal human gets a slide, sometimes it has way too many cells, and they're clumped up, so they have to literally understand the reason this area is dark isn't because it's bad, it's because there's a clump or there's mucous." He then explains, "Sometimes the cells, it will look good, but that's because there just aren't enough cells, and they can tell by the way they are that they didn't get a good sample."

He basically explains that the human is very good at differentiating all sorts of things that it's very hard to program this machine to do. That his machine would be particularly good at reading slides if the slide was well made, and his machine would be particularly bad at reading slides if it had to do all the things that humans do by applying their judgment to the slide. And he says, "I know you play with all these fluids and all this stuff, so you can help me do this."

So, okay. And it sounds pretty cool. And he said -- he described I think a number of different ways they do that. He said -- in fact, we recently saw an article where he described, I think incorrectly, but you can use these filter materials to get slides. There's different methods of collecting slides. In one of those reviews it's sort of like you push them through a filter, or you put a fluid with these slides on a filter, you push the liquid out, and you collect the slides, like the coffee grinds that are left on this side of the filter when the coffee comes through.

I said to him, "You're right. I do know how to solve this problem." Oh, by the way, not

just generally, I literally had, like the error thing, I had a solution for him on the shelf. The reason I particularly remember the meeting is, it's not that often that somebody comes in that you literally -- at least I thought -- I literally had a solution right there, a particular implementation of FMS.

I have to go off the subject just a little for a second here. We're making all these pumps for people. Lots of people make pumps. They deliver fluid. Very few, in fact at that time nobody, made pumps that in the middle of delivering fluid are going to suck it out. We don't do that. A lot of the pumps I made deliver stuff like chemotherapy. We made pumps for insulin. And you take a tiny needle and you put it under your skin, and it's okay for delivering insulin under your skin, not into a vein. In fact, it's preferential. That's the way diabetics -- it's not only preferential because it hurts less and is easier, it's preferential because it gets absorbed slowly.

There are a lot of drugs that are supposed to go directly into a vein, and if they don't go into a vein, you're in big trouble. Chemotherapy in

particular. There's vincristine, cisplatin, adriamycin, methotrexate, folic acid. Almost all the cytotoxic stuff you do not want to come out of the vein and go into tissue; it's bad. In fact, it's so bad the name for it in a hospital is called extravasation or infiltration. And if the needle -- you want a needle to be sharp to get into that vein, and then they tape it down. But if it's sharp enough to easily get in the vein, what if it punctures through the side of the vein and starts delivering the solution into tissue? That's extravasation. That's really bad.

I'm building pumps to make the stuff even more concentrated to give it to somebody so they can be ambulatory. So it's even harder to see, because you're not going to get big and swollen, because you're giving a small amount of fluid, and they're out somewhere.

So I had been working on something to detect infiltration. We have patents on something called an infiltration monitor. And the way it worked -- and I had spent two years on this before Stan ever showed up -- was supposing you have a needle in a vein. The way other people were trying,

guys like IMED, the big companies making pumps, the way they were trying to claim that they could detect infiltration was, if that needle came out of the vein and into the tissue, it's pumping at a known pressure. They put a pressure meter on the fluid line, and the pressure, let's say, for a given size needle at a given flow rate, there's some amount of pressure. And if the needle pops outs of the vein and goes into the tissue, the pressure might go up a little. So you can detect it. But there's so much noise, the difference in pressure is pretty small. And the fact is, by the time the pressure goes up, it's because you filled all the interstitial tissue with fluid that isn't being pulled away, it's probably too late anyway.

So I had decided since FMS can both pull and push and have pressure sensors, and we can talk about what FMS is, I said, "Every few seconds why don't we interrupt the flow into the patient and pull back a little?"

Now, if you've got fluid that's going in, and it's going into a vein where there's fluid, and you're pushing in and you're pulling back, whatever the positive pressure wave is, whatever the negative

pressure wave is, they look about the same. If the end of the needle punctures through the vein and goes into tissue, it might make the positive pressure a little higher than it was in the vein, probably not discernibly, maybe a little higher. But as soon as you go to pull back, you're going to get cells and stuff clogging up the end of that line, and the negative pressure wave will be completely asymmetric, completely different than the positive pressure wave, and you'll know something happened to your needle.

We had finished that project; I literally had some of those little machines sitting in my shop. "Stan, do you want to collect these cells on this filter with all these holes? Instead of going the way you think through the top, we can use our FMS system. I already have a way to use positive pressure. I already have a way to use negative pressure. We can suck these things up against your filter, which has a bunch of holes in it. We can look at the rate of change of pressure like my infiltration monitor. As these things clog this thing up, like on the infiltration monitor, we're going to see the rate of change of pressure get

slower and slower and slower. Whenever we reach whatever arbitrary point you want in terms of what the flow rate is, we will know we have that much of the filter clogged." Basically, it was an infiltration monitor adapted to his application.

I showed him this. I showed him an infiltration monitor where if you take the end of a needle, put it in water, pump in and out, take it out of water, put it into catsup, literally into catsup, that's the demonstration we did for Stan. And the pressure would go up a little bit trying to push the water into catsup, but as soon as it started to pull back, you get all sorts of alarms.

Stan loved it. And he said, "Can you build me a machine to use this technology to make slides?" And we said, "Yes, we could." And it would be a fun project; it would serve a lot of people. He was really smart; he was a fun engineer. Typically, my clients, I work with their engineers. But Stan was a very smart guy. His expertise was going to make his vision systems work. I was going to use our FMS Technology and build the rest of the machine to make his slides. And we agreed to do that for him, and we set out to do it.

And I don't know whether he paid -- he may have paid none of anything over the original 50 percent of the original budget, but he paid a few hundred thousand dollars over a period of a year or so, which covered some of the costs. He did.

Anyway, we set out and we started making this machine, and it worked pretty well.

Q. Now, let me go back for a second, Mr. Kamen. You mentioned FMS Technology. What does "FMS" stand for?

CHAIRMAN MILONAS: How much longer will direct take?

MR. BROMBERG: I think it will be perhaps another hour.

Q. What is FMS Technology, Mr. Kamen?

A. The words FMS are used by us and our clients, because it's not a thing -- you can't point to something. This cup is not FMS. But if I -- if this was a filter, and I put this in here and I sealed it and started sucking, and I could tell what amount of the holes I was filling in the bottom, because I'm reading the pressure gage and the length, I'd say, "Oh, that's an FMS system."

FMS stands for Fluid Management System. If

the bottom diaphragm was pumping in and out and there was an inlet and outlet going to a heart-lung machine, it would be FMS. Depending on what you're measuring and what your disposable is set up to do, we've used FMS for various kinds of projects. And it stands for Fluid Management System.

And the reason we say it's fluid management, sometimes you care about the volume, sometimes you care about the pressure, sometimes you care about the flow rate. Sometimes we use it in manifolds where we're pumping lots of different fluids for lots of different places to eliminate large pieces of equipment. So we've done a lot of projects that we lump into something called FMS.

Q. At the time you met with Stan, had you already worked on FMS projects?

A. For many years.

Q. Had you already obtained patents for FMS?

A. Yes. And in particular -- I'm sure you have them -- we had patents on the infiltration monitor, before we ever talked to Stan.

(Documents marked as Claimant Exhibits 217, 219, 240 and 242 in evidence)

Q. Let me hand you copies of Arbitration Exhibits 217, 219, 240 and 242 and ask if those are some of your DEKA patents on FMS Technology.

A. Pressure monitor. Yes, this is certainly one.

Q. What's the exhibit number on that one?

A. 217. Enhanced pressure management and flow control, 219. This is called FMS2; this is called FMS1 in our vernacular.

Q. Okay.

A. Oh, I'll go to this one first. This one is 242, and this is a general-purpose FMS1 for IV solutions. And this is the infiltration monitor.

Q. By the "infiltration monitor," you're referring to --

A. This is the device I was just describing to you that could tell when the end of a needle is no longer in a vein.

Q. Is that the '019 patent, sir, the infiltration monitor?

A. '019.

Q. Up at the top.

A. Yes. The last three digits of the patent.

Q. So that would be our Exhibit 240?

A. 240.

Q. So that's the infiltration monitor.

A. Yes.

Q. And Mr. Kamen, in those four patents can you tell what their priority date is, their filing date or the date that they claim back to?

A. The infiltration monitor, it says filed on March 3, 1987, but it says continuation-in-part number of something else, serial number.

CHAIRMAN MILONAS: Would it be fair to say all the filing dates precede your meeting with Mr. Lapidus in 1988 or '89?

THE WITNESS: Yes.

MR. BROMBERG: Thank you, Your Honor. In fact, all four of these have the same priority date of March 4, 1986.

Q. And now let's talk about issuance. The earliest one to issue, Mr. Kamen, I believe is the '451, which has an issue date of October 18, 1988.

A. '451. It has an issue date of October 18, 1988.

CHAIRMAN MILONAS: And that's prior to your working on this project with Mr. Lapidus?

THE WITNESS: Yes. We literally -- I mean,

again.

A. This seems all encompassing to me. If it's Cytyc Technology, if it's FMS, which is a system that uses solutions and filters, if it's one or the other or both, I get my 1 percent. That's the way I read that.

Q. I don't think there's any dispute, Mr. Kamen, that the provided language means if it falls into either or both of the camps of Cytyc or FMS Technology. My question is, in order for something to be a product disposable, it must both be a filter cylinder or similar disposable and utilize one of those two technologies or both, correct?

A. I believe what you just said is correct.

Q. Is the microscope slide a filter cylinder or similar disposable?

A. Well, it's certainly similar if you're using it to make a slide. If they sold it for some other purpose, it wouldn't be similar. If it's in a pouch with the rest of the stuff to do this job, it's similar.

Q. You were at Mr. Lapidus' deposition, correct?

A. I was there for part of it.

Q. Now, calling your attention, sir, to the 1993 License Agreement, I want to ask you -- and that's Exhibit 40. I want to ask you to take a look, sir, at Page 12 --

A. Yes.

Q. -- Section 13.5, which states, "This agreement constitutes the entire understanding of the parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating thereto." Do you see that?

A. Yes, I do.

Q. Mr. Kamen, what's your understanding of that term?

CHAIRMAN MILONAS: We can probably give you a lecture on merger clauses. Is that what you're --

ARBITRATOR MERHIGE: That's what he'd deserve.

MR. BROMBERG: I thought he could.

A. My guess is those guys could do a better job.

CHAIRMAN MILONAS: You got it. Sometimes.

Q. Now, you also mentioned when you referred to this agreement on cross, you mentioned the definition of "Cytyc Technology" --

EXHIBIT 6

Volume II
Pages 2-1 to 2-305
Exhibits-See Index

AMERICAN ARBITRATION ASSOCIATION

Case No. 11 Y 133 02624 03

- -x

DEKA PRODUCTS LIMITED PARTNERSHIP,
Claimant,

vs.

CYTYC CORPORATION,
Respondent.

- -x

BEFORE: Hon. E. Leo Milonas, Chairman
Hon. Robert R. Merhige, Jr., Member
Hon. Vincent L. McKusick, Member

PRESENT:

Bromberg & Sunstein LLP
(by Lee Carl Bromberg, Esq. and
Erik Paul Belt, Esq.)
125 Summer Street, Boston, MA 02110-1618,
-and-
DEKA Research & Development Corporation
(by Maureen K. Toohey, Esq.)
340 Commercial Street, Manchester, NH
03101-1129, for the Claimant.

(Continued on Page 2-2)

PRESENT (Continued):

Howrey Simon Arnold & White, LLP
(by Matthew M. Wolf, Esq., Marc A. Cohn, Esq. and Nabina Sinha, Esq.)
1299 Pennsylvania Avenue, N.W.,
Washington, DC 20004-2402,
-and-
Cytyc Corporation (by Mark J. Casey, Esq.)
85 Swanson Road, Boxborough, MA 01719,
for the Respondent.

ALSO PRESENT: Dean Kamen
Brendan Duffy
Robert Goldscheider
Amy West
Iain Cockburn
Yvette Thomas
John Turnbull

(Anne H. Bohan, Registered Diplomate Reporter)

-held at-
American Arbitration Association
133 Federal Street
Boston, Massachusetts
Tuesday, December 14, 2004
8:57 a.m.

later.

Q. Approximately when was this meeting?

A. On or about May 21st.

Q. Who was there?

A. Again, from DEKA it was me and Charlie Grinnell, our engineering manager. And from Cytyc it was Mike Gilgun again, Steve Cavazza again. And then Bob Bowen, who was their CFO at the time.

Q. What do you recall about this meeting, Mr. Duffy, about what was discussed?

A. Well, probably my number one recollection from the meeting -- and it's because I was stunned by it -- was something that Bob Bowen said while we were meeting. After we had a discussion on relative value, et cetera, he told me to get up to the whiteboard and started telling me, "This is the method that we use. We use a relative cost -- a relative cost ratio to determine this. It's a simple and easy method. It's better than your method. It's the method we're going to use."

And then he said something that stunned me. He said, "You need to understand, Mr. Duffy, that the underlying data here, the pricing data, is under my control. And right now I'm redoing the pricing

on all of our products, a new pricing strategy, so it's very easy for me to change the underlying data. If you come up with a method that changes the royalty stream, you need to understand that I can change the underlying data in order to put your royalty stream to the level that I think it ought to be at."

ARBITRATOR McKUSICK: Who told you that?

THE WITNESS: That was Bob Bowen, their CFO.

Q. How did he appear when he told you that?

A. He was, throughout the meeting, right up front, very confrontational. At this point he was pretty heated, and he was up writing this example on the board and telling me, "This is the way it's going to be. And you need to understand that I can control this data, and I'll put the revenue royalty stream where I think it ought to be."

Q. What did he explain to you about why he thought the cost-ratio methodology to calculate the royalties was appropriate?

A. He used the term that we heard yesterday, this "principled approach," and he said the

in this case, at the time I wrote this letter.

Q. As of the time you wrote this letter, had you told Cytyc that it had not appropriately applied the License Agreement royalty structure in any way?

A. At the first meeting we had, yes, we had a discussion about what the License Agreement said and the fact it covers, specifically with respect to disposables, the filter cylinder and similar disposables. It was my opinion that "similar disposables" means disposables that use the FMS and Cytyc technology. They had a different view of that and didn't want to discuss that issue any more. So I went on to other topics to try to understand their business.

Q. Do you recall at your deposition, Mr. Duffy, I asked you whether you ever told Cytyc that it was DEKA's view that Cytyc should pay 1 percent on the entire kit and your answer was no?

A. I remember that, yes.

Q. Now, three months have passed since Ms. Singleton's letter, looking at Exhibit 257, and you've had an in-person meeting with Cytyc personnel regarding the royalty, yet this letter still does not assert Cytyc's payment on only the filter

foundation very well. You took notes at the third meeting, correct, Mr. Duffy?

A. I did.

Q. And you destroyed those notes?

MR. BELT: Objection.

CHAIRMAN MILONAS: Overruled.

A. I no longer have those notes. I would have thrown them out.

Q. So it's your testimony that Mr. Bowen said that he was going to manipulate data; is that correct?

A. He told me that he had control of the underlying data, and he said, "In fact, I'm right now redoing all the pricing of all our products, so you need to understand that if you come up with a method that gives you a royalty that I don't agree with, I will change the underlying data, or I can change the underlying data to keep your royalty at the level that I think it ought to be." That's what he said.

Q. Are you aware of any document that suggests that Mr. Bowen threatened to manipulate data?

A. Yes.

Q. What is that?

A. The notes that Mr. Grinnell took at that meeting.

Q. We'll talk with Mr. Grinnell about those notes. Does the word "data" appear anywhere in Mr. Grinnell's notes?

A. I would have to look at them to answer that question.

Q. Why don't we just talk with Mr. Grinnell about his own notes.

A. Okay.

Q. If we could look at Exhibit 113.

A. What is that?

Q. The October 22, 2003 letter.

Mr. Duffy, Exhibit 113 is the correspondence in which DEKA threatened to initiate this arbitration, correct?

A. I would have to read through this letter to answer that. It says that the letter is a "Demand For Arbitration of Royalty Dispute."

Q. Are you aware of a single document before October 22, 2003, in which DEKA asserts that Cytyc must pay a royalty based on the entire revenue base of the ThinPrep Pap Test Kit?

A. A written document?

A. I don't have a technical basis on which to answer that question.

MR. WOLF: I have no further questions.

CHAIRMAN MILONAS: Thank you. Anything?

MR. BELT: I'll ask a few questions, Your Honor. Thank you.

CHAIRMAN MILONAS: Why? You've had a long direct, the cross was very short, and I hope it's only focused on these questions.

MR. BELT: Absolutely.

CHAIRMAN MILONAS: If you go beyond that, the guillotine will fall.

MR. BELT: My wife won't like that, but yes.

ARBITRATOR MERHIGE: I have one last question. Did you throw away all of your notes?

THE WITNESS: Yes.

REDIRECT EXAMINATION

BY MR. BELT:

Q. Why did you throw away your notes?

A. I reviewed those with the other members of the management team at DEKA when I returned, and I wouldn't customarily keep my notes.

Q. That's your practice, not to keep the

notes?

A. Correct.

Q. Mr. Wolf asked you about the SEC or the Annual Reports. Have you actually looked at any of these annual reports?

A. Since this litigation has started, yes.

Q. Do any of those annual reports say that Cytyc is using a cost-ratio method to calculate the royalty?

A. There's nothing in there about using a cost-ratio method, no.

Q. Again, for any of the SEC filings that you've looked at, the same question.

A. There's nothing in there that discusses a cost-ratio method.

Q. You were asked about the January 29th letter that you wrote to Ms. Singleton. Why did you take about two months from the time that you got the November 27th letter to write that letter?

A. Well, just in general terms, let's say I got the November 27th letter at the end of November, November 30th or December 1st. One of the things I needed to do was discuss that with Mr. Kamen. I think it was December 1st or December 2nd was the

A. Bob Bowen.

Q. Then you can continue.

A. Then it continues, "Bob lays out method as described and says that if we demand a shift in method, he will just adjust pricing strategies to put royalty where he thinks it's appropriate."

Q. How did he appear to you when he said that?

A. He appeared very aggressive and agitated, as he had appeared through the whole meeting.

Q. There's a statement right after that "Bob states." Could you read that.

A. Yes. "Bob states for first time that they sell each."

Q. What is that referring to?

A. I made that notation. I think I've said already that we had been repeatedly told that although they list on price lists and in their royalty accounting that they break these things out separately, they claim to have never -- to never sell those four items separately, but he made the straight statement for the first time we had heard this that they do sell these things separately.

MR. BELT: Thank you. I have no other questions.

A. Exactly, sir.

Q. How so?

A. The words "similar disposables" are crucial in this case. They've been mentioned by the attorneys; they've been mentioned by witnesses. And if one understands the concept of this patented FMS Technology system, together with the Cytyc Technology, one realizes that if a component is affected by either FMS or Cytyc Technologies, then it becomes a disposable, if it's part of this unit. It doesn't have to look like a filter. It doesn't have to look like a cylinder. It can look like a collection device or the other things as well.

If something is related and they had the same grandfather, the grandchildren may look very different, but they're all part of the same family. And I believe that we have a system here, this product, and it has a trunk, and that trunk is either FMS or Cytyc Technologies. And if those components are influenced by FMS or the other, then they become, within the definition of "disposables," they are "similar disposables." And therefore, this system is something which qualifies DEKA to receive

EXHIBIT 7

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Pages 3-1 to 3-166
Exhibits-See Index

AMERICAN ARBITRATION ASSOCIATION

Case No. 11 Y 133 02624 03

- -x

DEKA PRODUCTS LIMITED PARTNERSHIP,
Claimant,

vs.

CYTYC CORPORATION,
Respondent.

- -x

BEFORE: Hon. E. Leo Milonas, Chairman
Hon. Robert R. Merhige, Jr., Member
Hon. Vincent L. McKusick, Member

PRESENT:

Bromberg & Sunstein LLP
(by Lee Carl Bromberg, Esq. and
Erik Paul Belt, Esq.)
125 Summer Street, Boston, MA 02110-1618,
-and-
DEKA Research & Development Corporation
(by Maureen K. Toohey, Esq.)
340 Commercial Street, Manchester, NH
03101-1129, for the Claimant.

(Continued on Page 3-2)

PRESENT (Continued):

Howrey Simon Arnold & White, LLP
(by Matthew M. Wolf, Esq., Marc A. Cohn, Esq. and Nabina Sinha, Esq.)
1299 Pennsylvania Avenue, N.W.,
Washington, DC 20004-2402,
-and-
Cytyc Corporation (by A. Suzanne Meszner-Eltrich, Esq. and Mark J. Casey, Esq.)
85 Swanson Road, Boxborough, MA 01719,
for the Respondent.

ALSO PRESENT: Dean Kamen
Brendan Duffy
Amy West
Iain Cockburn
Patrick Sullivan
Yvette Thomas
John Turnbull

(Anne H. Bohan, Registered Diplomate Reporter)

-held at-
American Arbitration Association
133 Federal Street
Boston, Massachusetts
Wednesday, December 15, 2004
9:01 a.m.

quantity of 33 up at the top. Do you see that, sir?

A. Yes, sir.

Q. So are those the machines that you sold?

A. I sold 24 and an associate of mine sold around 12.

Q. So that looks like we've accounted for them on here, correct?

A. Yes, sir.

Q. Then do you see in the line below that it says "Disposables" and then in parentheses "(Total)"? Do you see that, sir?

A. Yes, I do.

Q. Do those disposables include preservative solution at that time, sir?

A. I have no basis to know what is in that disposable line item. I would imagine that it would include preservative -- no. I don't know; I don't know.

Q. You have no way of knowing?

A. I have no way of knowing what was included or not included in that line item.

Q. But it's clear that Mr. Lapidus paid DEKA 1 percent on the net sales of the processors and the disposables, correct?

A. But I don't know what the definition of "disposables" is, as evidenced on this sheet.

Q. Why do you suppose he puts the word "total" in after "disposables"?

A. You'd have to ask Stan.

Q. At least on the face of this document, it says "Disposables (Total)," and then 1 percent is paid on the sales dollars applicable to that item, correct?

A. Correct. There's also some interesting additional commentary on the bottom part of that. I have no knowledge of what that is either.

ARBITRATOR MERHIGE: Keep your voice up.

THE WITNESS: Yes, sir.

Q. Now, I think you've told us about '96. How about -- there was a change in '96 to this 20 percent method, correct?

A. I would not characterize it as a change to the 20 percent method.

Q. Well, it certainly is a difference to multiply the net sales by .2 percent as compared to multiplying them by 1 percent that we see on Exhibit 176.

A. Yes.

Q. So that's different.

A. No. I think there's a distinction that needs to be drawn here. The non-gyn filters would have been subject to the 1 percent per the DEKA royalty agreement. The gyn filters would also be subject to 1 percent of the gyn filter component. And we calculated that to be using the relative cost method at 20 percent. So in terms of -- there was not a change in methodology; it was a change in the product that was approved. So we had to come up with some allocation to apportion to the filter. And the only reasonable method that I could ascertain in 1996 was the cost.

Q. But it's true, isn't it, you just told us a couple of minutes ago, you can't really recall what was done. So you're just speculating here, isn't that --

A. The report you showed me earlier, counselor, showed for the non-gyn on this exhibit, we paid at 100 percent. And for the preservative solution, we paid at zero percent. So as far as I know, between the time of 1991 through 1996, we paid DEKA 1 percent of the filter sales associated with non-gyn. That's on information and belief.

Q. You don't know; is that fair to say?

A. This document would support, at least in that instance, we paid 1 percent on non-gyn filters.

Q. This document would support that for 1991, you paid 1 percent on total disposables, correct?

A. It doesn't say that, counselor.

Q. What does it say? Doesn't it say "Disposables (Total)"?

A. I don't know what is in that line item.

Q. Okay. So whatever it means, it means.

A. But in the previous document that you showed me, the royalty report clearly stipulates for the non-gyn TransCyt filters, it's paid at 100 percent.

CHAIRMAN MILONAS: What else could it mean if it doesn't mean that? What else could it mean?

THE WITNESS: It could mean -- I don't know whether the disposables only meant the filters or whether it included the preservative solution. I have no way to determine that.

CHAIRMAN MILONAS: So what does the first item mean? Are you saying the first item is the "system," quote, and the second item is only the filters?

EXHIBIT 8

Volume I
Pages 1 to 105
Exhibits-See Index

AMERICAN ARBITRATION ASSOCIATION

Case No. 11 Y 133 02624 03

- -x

DEKA PRODUCTS LIMITED PARTNERSHIP,
Claimant,

vs.

CYTYC CORPORATION,
Respondent.

- -x

DEPOSITION OF STANLEY N. LAPIDUS, a witness called on behalf of the Claimant, taken pursuant to Rule 30 of the Federal Rules of Civil Procedure, as well as the applicable provisions of the American Arbitration Association Commercial Rules of Arbitration, before Anne H. Bohan, Registered Diplomate Reporter and Notary Public in and for the Commonwealth of Massachusetts, at the Offices of Helicos BioSciences Corporation, One Kendall Square, Building 200, Cambridge, Massachusetts, on Tuesday, September 7, 2004, commencing at 1:22 p.m.

PRESENT:

Bromberg & Sunstein LLP
(by Erik Paul Belt, Esq.)
125 Summer Street, Boston, MA 02110-1618,
-and-
DEKA Research & Development Corporation
(by Maureen K. Toohey, Esq.)
340 Commercial Street, Manchester, NH 03101-1129, for the Claimant.

(Continued on Page 2)

PRESENT (Continued):

Howrey Simon Arnold & White, LLP
(by Matthew M. Wolf, Esq.)
1299 Pennsylvania Avenue, N.W.,
Washington, DC 20004-2402,
-and-
Cytyc Corporation (by Mark J. Casey, Esq.)
85 Swanson Road, Boxborough, MA 01719,
for the Respondent.

Sullivan & Worcester LLP
(by Richard S. Sanders, Esq.)
One Post Office Square, Boston, MA 02109,
for the Deponent.

ALSO PRESENT: Thomas C. Meyers, Esq.
Dean Kamen

A. No.

Q. Thank you. Was it your regular practice to record in an engineering notebook your day-to-day engineering activity at Cytyc?

A. It was my irregular practice to do so.

Q. What would prompt you to make a record in your engineering notebook at Cytyc?

MR. SANDERS: Objection. You can answer.

THE WITNESS: I can answer, okay.

A. If I thought I had invented something, or I was perplexed by something and needed to analyze it.

Q. Now, do you know Dean Kamen?

A. I do.

Q. Can you tell me when was the first time you met him?

A. I'm going to say in 1979 or 1980.

Q. What were the circumstances?

A. My banker, a guy named Bob Wheeler at the Bedford bank, introduced us.

Q. Would you regard Dean Kamen as a friend of yours?

A. I would, yes.

Q. What was your occupation at the time you met Mr. Kamen?

A. I do.

MR. SANDERS: On this issue?

MR. BELT: On this issue.

A. I do.

Q. Can you tell me, where was the meeting?

A. Yes. At Dean's office.

Q. At Dean's office. Again, sometime in the fall of 1988?

A. To the best of my recollection.

Q. Do you recall what you discussed at that meeting?

A. I do.

Q. Can you tell me that.

A. I had mentioned to Dean that I was working on a device to do analysis of slides, a computerized image analysis system. That we had gone with it as far as we could, and that we needed a sample preparation device which would lay cells in a single layer onto a slide.

I think I also mentioned to Dean that people had been working on this for 30 years with no success in developing an industrial version of this idea, and that I had this idea of sucking cells against a filter and using the differential pressure

across this filter to measure the concentration of cells, but that I had no experience in how to do this and thought that Dean could help.

Q. Do you recall what Mr. Kamen said in response to that?

A. Yes. He was quite astonished. He said he had been working on the technology to do just this, a pumping technology to do just this in an unrelated product area.

Q. And did he give that pumping technology a name?

A. He called it FMS.

Q. As a result of this discussion -- well, first of all, let me ask you, did you discuss anything else at this meeting?

*A. I think after Dean described the existence of FMS, we ended the meeting. He wanted to go think about if we should enter into a business relationship or not.

Q. Did you enter into a business relationship with Dean?

A. We did; we did.**

Q. Approximately how far after this meeting did you enter into such a relationship?

Agreement, you'll see that in 5.01, where it says, "DEKA has developed the Products, and Cytyc hereby acknowledges that the Products' concept and design are acceptable to Cytyc," do you know what that is a reference to?

A. No.

Q. Would you regard DEKA's contribution to the ThinPrep processing system as valuable?

A. Yes.

Q. How so?

A. For two reasons. Reason one is, I had no idea how to implement the thing, the invention of sucking cells against a filter and measuring differentials in concentration. And I had no credibility with investors and I was in fund-raising mode. And so Dean's credibility as a gizmo guy added -- it was instrumental in raising the Series A money.

Q. Do you recall how much you raised in that Series A?

A. I think it was $5 million; I don't recall precisely.

Q. So Dean contributed some credibility to the investment process, correct?

A. Yes.

Q. And then what did he contribute to the implementation of the ThinPrep processor?

A. In addition to the license of the FMS technology itself, considerable know-how. I had spent days at DEKA with Dean's team evaluating the test bed and working closely with Rick Villeneuve, who is listed on the invention here, with Dean, and with a guy Normand -- Gerry Normand, perhaps -- a machinist who had made the assembled filter holder thingy.

Q. How was that valuable?

A. It was important. It was essential for the subsequent implementation of the product, so that when we hired Lew Polk, who designed the physical instrument as described in the patent, the test bed was operational, and we had proven to the investors that we could suck cells onto the filter in measured concentration.

MR. BELT: Do you want to take a five-minute break? Is that good?

MR. SANDERS: Sure.

MR. BELT: I have nothing further, and I'll yield to Cytyc. Thank you for your appearance

MR. WOLF: He's just saying that so the court reporter doesn't have to type what you say.

A. I have no understanding what that sentence means.

Q. You rejected the proposal on the first page of the document, correct?

A. I can't believe that I would have agreed to it.

Q. Why is that?

A. Because it would be a bad proposal. It would either be unfair to Cytyc or unfair to Dean.

Q. Why would it be unfair to Dean?

A. If the disposable price turned out to be greater than $3.50, or if the instrument price would have turned out to be greater than that $18,500, it would have been worse for Dean, and if the prices were lower for Cytyc, it would be worse for Cytyc.

Q. "The disposable" referenced in Exhibit 16 is the filter, correct?

A. Based on the wording in the second paragraph, the answer to your question would be yes.

Q. Do you have any recollection of ever having a discussion with DEKA of how royalties would be determined if the filter were packaged with

Q. Do you know what products were sold to be used with the ThinPrep processor?

MR. SANDERS: At that time?

MR. WOLF: At that time, thank you.

A. I don't recall.

Q. Was the filter used?

A. It was.

Q. At that time?

A. It was.

Q. Was the preservative solution sold at that time?

A. It was.

Q. Were there slides sold at that time?

A. I don't recall when we began selling slides.

Q. Are you aware of anything unique about the slides that Cytyc sells with the ThinPrep processor kit?

A. Yes.

Q. What's unique, to your knowledge?

A. The slides have properties which assure that cells stick to the slides.

Q. Do you know when Cytyc first became aware of the potential of making slides with those special

Cytyc is going to assert the privilege, we're going to respect that. To the extent we're going to respect that is to the extent that the conversations that took place took place about events that occurred while Mr. Lapidus was at Cytyc. If events occurred after and they had conversations after, that, to me, is fair game.

So I don't know when -- establish whether the substance of the conversation was about events that occurred while he was at Cytyc.

BY MR. BELT:

Q. Let me ask this question: Did you talk to Mr. Kamen about your conversation with the people at Cytyc?

A. I did not.

Q. Okay. Do you hold the view that Mr. Kamen's contribution to the ThinPrep system was important?

A. Extremely important.

Q. Why extremely important?

A. As I had mentioned before, both from a technology perspective, from an implementation perspective, because I knew nothing at all about moving small volumes of fluid, and from a

credibility perspective, Dean's contribution was invaluable.

Q. Do you have Defendant's Exhibit 3 in front of you?

What was the basis for your -- on the second page, Subparagraph (a), what was the basis for your stating that word "fee" should be "free" as in a "royalty-free license"?

A. Ah. I remember, the first time I had ever heard that phrase. So you're asking me what was my basis for stating that in response to an earlier question?

Q. Absolutely.

A. The first time I ever heard the phrase "royalty-free license" was actually from Dean. I've never heard it from anyone else, ever, and I've never seen "royalty-fee license." So I presume it's a typo.

Q. Was it your understanding at that point that DEKA would own any patents resulting from its work related to the ThinPrep system?

A. My understanding was that DEKA owned the FMS patents, and we acknowledged DEKA's ownership of those by doing a license. That Dean was a

EXHIBIT 9

Volume I
Pages 1 to 158
Exhibits 26 to 34

AMERICAN ARBITRATION ASSOCIATION

Case No. 11 Y 133 02624 03

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DEKA PRODUCTS LIMITED PARTNERSHIP,
Claimant,

and

CYTYC CORPORATION,
Respondent.
- - - - - - - - - - - - - - - - - - -x

DEPOSITION OF CYTYC CORPORATION by its designee HUGH VARTANIAN, a witness called on behalf of the Claimant, taken pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, as well as under applicable provisions of the American Arbitration Association Commercial Rules of Arbitration, before Susan J. Cataldo, Professional Shorthand Reporter and Notary Public in and for the Commonwealth of Massachusetts, at the Offices of Bromberg & Sunstein LLP, 125 Summer Street, Boston, Massachusetts, on Thursday, September 2, 2004, commencing at 10:00 a.m.

PRESENT:

Bromberg & Sunstein LLP
(by Erik Paul Belt, Esq.)
125 Summer Street, Boston, MA 02110-1618,
- and -
DEKA Research & Development Corporation
(by Maureen K. Toohey, Esq.)
340 Commercial Street,
Manchester, NH 03101-1129,
for the Claimant.

(Continued)

PRESENT (Continued):

Howrey Simon Arnold & White
(by Matthew M. Wolf, Esq., and
Marc A. Cohn, Esq.)
1299 Pennsylvania Avenue, NW,
Washington DC 20004-2402,
- and -
CYTYC Corporation (by Mark J. Casey,
Vice-President, Deputy General & Chief
Patent Counsel) 85 Swanson Road,
Boxborough, MA 01719,
for the Respondent.

* * * * *

A. Okay.

Q. -- four or five steps that you've listed, are those all controlled by FMS?

A. As I said, my understanding of the FMS is the pressure and vacuum sources (indicating). That's what we used the term FMS around. The sipping process we never spoke of as being part of the FMS. It's a separate process.

Q. Who -- if you know, who contributed FMS to the ThinPrep Processor?

A. I don't know the specific parties. There were, you know, cylinders and pressure tanks when I started working with DEKA, to my recollection.

Q. Is your recollection that FMS came from DEKA?

A. It was there when I started working with them.

Q. Is FMS a key component of the ThinPrep Processor?

A. The processes that we described there depends on those pressure vacuum sources to effect the various pieces of the cycle in the instrument (indicating).

Q. So would that be, yes, that those processes

depend on FMS?

MR. WOLF: Objection. That wasn't the question you asked.

A. Yes. Please, rephrase that.

Q. Fine. I just want to clarify it.

A. Okay.

Q. I had asked do those -- is FMS a key component of the ThinPrep Processor?

MR. WOLF: And he gave you an answer to that question.

A. Yes. And to repeat, the supply of pressure and/or vacuum to the instrument is a key part of the processes which I described there (indicating).

Q. Okay. To the best of your recollection, can you tell me every component and function that DEKA contributed to the workings of the FM -- strike that -- to the workings of the ThinPrep Processor?

MR. WOLF: As it currently exists?

MR. BELT: Yes.

A. Until the intersection of what was the -- to rephrase, the intersection of what was there, to my recollection, when I started and what lives in the instrument now?

Q. Yes.

EXHIBIT 10

American Arbitration Association
Dispute Resolution Services Worldwide

Northeast Case Management Center
Catherine Shanks
Vice President

Christopher Fracassa, Yvonne Nelson
Assistant Vice Presidents

950 Warren Avenue, East Providence, RI 02914
telephone: 866-293-4053 facsimile: 401-435-6529
internet: http://www.adr.org/

February 23, 2005

Via Facsimile

Lee Carl Bromberg
Bromberg & Sunstein LLP
125 Summer Street
Boston, MA 02110

Mark J. Casey, Esq.
Assistant General Counsel
Cytyc Corporation
85 Swanson Road
Boxborough, MA 01719

Matthew M. Wolf and Marc A. Cohn, Esq.
Howry, Simon, Arnold & White, LLP
1299 Pennsylvania Avenue, NW
Washington, DC 20004

Re: 11 133 Y 02624 03
DEKA Products Limited Partnership
and
Cytyc Corporation

Dear Parties:

Inasmuch as there is a vacancy in the arbitration panel in the above matter, the chair has requested that the parties advise, in writing, if they are willing to go forward with 2 arbitrators in the above matter, pursuant to rule R-19(b) of the Commercial Arbitration Rules and Mediation Procedures (Including Procedures for Large, Complex Commercial Disputes) Amended and Effective July 1, 2003. The parties are to submit said information on or before February 28, 2005.

Sincerely,

Paula C. Dubois
Case Manager
401431 4789
duboisp@adr.org

Katharine M. Legeros
Supervisor
401 431 4714
LegerosK@adr.org

cc: HON Vincent L. McKusick
E. Leo Milonas, Esq.

American Arbitration Association
Dispute Resolution Services Worldwide

950 Warren Avenue
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Fax 401 435 0125

February 23, 2005

TO:	Lee Carl Bromberg & Eric Belt	FAX: 617-443-0004
	Mark Casey	508-263-2996
	Matthew Wolf and Marc Cohn	202-383-6610
CC:	E. Leo Milonas	212-858-1500
	Vincent McKusick	207-791-1350
FROM:	Paula Dubois Case Manager	

PAGES: (including cover) 2

RE: 11 Y 133 02624 03

EXHIBIT 11

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BROMBERG & SUNSTEIN LLP

ERIK PAUL BELT
T 617 443 9292 x260
EBELT@BROMSUN.COM

February 28, 2005

VIA FACSIMILE AND
CONFIRMATION BY MAIL

Hon. E. Leo Milonas
Pillsbury Winthrop, LLP
1540 Broadway
New York, NY 10036

Hon. Vincent L. McKusick
Pierce Atwood
One Monument Square
Portland, ME 04101-1110

Re: Arbitration *of DEKA Products Limited Partnership and Cytyc Corporation*,
AAA Case No. 11 Y 133 02624 03
Our File 1062/507

Dear Honorable Panel:

DEKA Products Limited Partnership and its counsel are saddened to hear of Judge Merhige's passing. Please extend our sympathies to his family and colleagues.

Under the circumstances, and in accordance with AAA Commercial Arbitration Rule R-19(b), the most reasonable way to proceed is to continue with Judges Milonas and McKusick and to have them determine this dispute. There is no need to appoint a third panelist. This case has now been fully litigated, the final hearing has been held, and the post-hearing briefs have been submitted. The appointment of a new panelist at this advanced stage will add unnecessary expense and will delay final resolution of this matter.

Rule R-19(b) provides that when the vacancy in the arbitration panel occurs "after the hearings have commenced, the remaining arbitrator or arbitrators may continue with the hearing and determination of the controversy, unless the parties agree otherwise." Courts have commented that this provision allows the panel to continue without a third panelist. *See, e.g., U.S. Energy Corp. v. Nukem, Inc.*, Nos. 03-1444 and 03-1451, 2005 WL 428913 at * 10 (10th Cir., Feb. 24, 2005) (". . . the two surviving members of the panel could continue pursuant to AAA Rule 19(b) without a third member").

Accordingly, DEKA is willing to go forward with two arbitrators.

Thank you for your consideration of this matter.

Very truly yours,

Erik Paul Belt
EPB/id
Enclosure
cc: Matthew M. Wolf, Esq.
Marc A. Cohn, Esq.
Ms. Paula C. Dubois
Ms. Katharine M. Legeros

EXHIBIT 12

HOWREY SIMON ARNOLD & WHITE
HOWREY LLP
ATTORNEYS AT LAW

1299 PENNSYLVANIA AVE., NW
WASHINGTON, DC 20004-2402
PHONE 202.783.0800
FAX 202.383.6610
A LIMITED LIABILITY PARTNERSHIP

February 28, 2005

VIA FACSIMILE

Hon. E. Leo Milonas
PILLSBURY WINTHROP, LLP
1540 Broadway
New York, New York 10036
Fax: (212) 858-1500

Hon. Vincent L. McKusick
PIERCE ATWOOD, LLP
One Monument Square
Portland, ME 04101
Fax: (207)-791-1350

Re: Arbitration of *DEKA Products Limited Partnership and Cytyc Corporation*, AAA File No. 11 Y 133 02624 03

Dear Honorable Panel:

I write in response to the AAA's letter dated February 23, 2005, and we express our condolences on the recent passing of Judge Merhige.

AAA Rule 19 is the same today in relevant parts it was in 1993 when the Agreement at issue was executed. That Rule provides that the Panel "may" continue to decide the case unless the parties agree otherwise. It is thus entirely within the Panel's discretion to decide how to proceed.

In exercising its discretion, Cytyc believes that the Panel should be guided by recent authority analogous to the unfortunate circumstances present here. For example, in *Success Village Apts., Inc. v. Amalgamated Local 376, UAW*, 2005 U.S. Dist. LEXIS 2288 (D. Conn. 2005) (attached hereto), one member of a three-Judge panel passed away "after the panel heard all evidence and argument, discussed the issue, and reached a final decision on the submitted issues." *Id.* at *6. The court held that, as the Panel conferred and discussed the views of all the members, it did not need to select a new arbitrator to fill the vacancy. The court reasoned that after hearing the evidence and making its decision, the Panel had fulfilled its duty to decide the issues and all that was left was to draft and sign a ruling. The arbitration award from the two remaining panelists was binding.

HOWREY LLP ATTORNEYS AT LAW

Thus, assuming the Panel received the views and input from Judge Merhige, then the policy in *Success Village* suggests that it would be unnecessary to select a new Arbitrator.

Thank you for your attention to this matter.

Sincerely,

Matthew M. Wolf

cc: Erik P. Belt, Esq.
Paula C. Dubois

HOWREY SIMON ARNOLD & WHITE HOWREY ATTORNEYS AT LAW

1299 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20004-2402
PHONE: 202.783.0800 • FAX: 202.383.6610

FACSIMILE COVER SHEET

DATE: 2/28/05

TO: NAME: Erik Belt
COMPANY: Bromberg & Sunstein
FAX NUMBER: 617-443-0004 PHONE NUMBER:
CITY:

FROM: NAME: Mac Cohn
DIRECT DIAL NUMBER: 202 383 6858 USER ID: 4881

NUMBER OF PAGES, INCLUDING COVER: 3 CHARGE NUMBER: 01990.0003

☐ ORIGINAL WILL FOLLOW VIA:

☐ REGULAR MAIL ☐ OVERNIGHT DELIVERY ☐ HAND DELIVERY ☐ OTHER:

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SUPPLEMENTAL MESSAGE:

IF THERE ARE ANY QUESTIONS OR PROBLEMS WITH THE TRANSMISSION OF THIS FACSIMILE, PLEASE CALL 202.383.7137.

EXHIBIT 13

AMERICAN ARBITRATION ASSOCIATION

DEKA PRODUCTS LIMITED PARTNERSHIP, Claimant v. CYTYC CORPORATION, Respondent.	Case No. 11 Y 133 02624 03

[PROPOSED] SCHEDULING ORDER

In accordance with the preliminary hearing on May 5, 2004, the order of the Arbitration Panel, and the parties' agreement, the parties jointly request that the Panel approve the following schedule for the conduct of this arbitration:

1. Except as stated below, the parties agree to abide by the Federal Rules of Civil Procedure as to the conduct of discovery, including, e.g., limits on the number of depositions and interrogatories. The parties also agree to participate in the Accelerated Exchange Program.

2. The parties waive the requirements of F.R.C.P. 26(a)(1) regarding automatic initial disclosures. The parties waive the requirement of F.R.C.P. 26(d) governing the timing of discovery to the extent it requires automatic disclosure and approval of a scheduling order before a party may seek further discovery requests. That is, the parties may immediately begin serving discovery requests upon signing this stipulated proposed scheduling order.

3. All fact discovery shall be completed by **September 10, 2004**. Thus, all paper discovery requests must be served at least 30 days before the discovery deadline.

4. The parties may subpoena any person to produce documents, appear at a deposition, or attend a hearing, in accordance with Rule R-31. The Arbitration Panel, by approving this scheduling order, approves in advance any such third-party subpoena, subject to the following condition. Prior to serving a subpoena for discovery on any third party, the party seeking such discovery shall provide a copy of the subpoena, discovery requests, and associated papers to the non-propounding party and allow the non-propounding party three (3) days to object to such discovery. Should no objection be made within the prescribed time, the subpoena may be served. In the case of timely objection, the subpoena may not be served absent leave from the arbitration panel or the parties' mutual consent.

5. Expert discovery shall be completed by **November 1, 2004**. All initial expert reports shall be served by **September 20 2004**. All rebuttal reports shall be served by **October 4, 2004**.

6. The parties shall specify their claims and counterclaims by **November 1, 2004**. The parties shall also file with the Panel a stipulation of uncontested facts on that date.

7. By **November 12, 2004**, the parties shall exchange and file with the Arbitration panel pre-hearing briefs, not to exceed 20 pages, setting forth the party's position and the supporting arguments and authority. At the same time, the parties shall exchange copies of all exhibits they intend to submit at the hearing (or, when appropriate, make them available for inspection). Exhibits shall be pre-marked for identification and tabbed in 3-ring binders to the extent possible. The parties shall cooperate in compiling a set of joint exhibits and shall file with the Panel key documents.

8. The parties shall identify all witnesses they intend to call at the hearing, along with a brief description of their expected testimony and written C.V. of experts, by **November 29, 2004**.

9. A final hearing on all matters shall be held on **December 13-17, 2004**. The hearing shall be held at the AAA Hearing Center, 133 Federal Street, Boston, MA. The hearing will be held from 9:00 am to 5:30 pm each day. Each side will have 18 hours to present its case, including direct and cross-examinations and a 15 minute opening per side. The time will be kept according to a "chess clock" procedure. The parties will evenly share the cost of the transcript.

10. The parties shall file post hearing briefs, not exceeding 30 pages, by **January 14, 2005**.

11. For purposes of this arbitration, papers are "filed" with the Arbitration panel by sending the papers by priority overnight delivery to each of the three panelists, at their designated offices. Papers must be sent so as to be received by any deadlines specified above. In addition, the parties agree to serve each other in the most expeditious manner possible, as, for example, by fax or e-mail to the designated opposing counsel with a hard copy sent by priority overnight delivery.

DEKA PRODUCTS LIMITED PARTNERSHIP

By its attorneys,

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Date: May 24, 2004

APPROVED:

By: _____
Arbitrator

6/2/04

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By its attorneys,

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EXHIBIT 14

US005185084A

United States Patent [19]

Lapidus et al.

[11] Patent Number: 5,185,084

[45] Date of Patent: Feb. 9, 1993

[54] METHOD AND APPARATUS FOR CONTROL OF FLOW THROUGH A FILTER CHAMBER BY MEASURED CHAMBER EQUILIBRATION PRESSURE

[75] Inventors: Stanley N. Lapidus; Dean Kamen; Richard R. Villeneuve, all of Bedford, N.H.; Lewis T. Polk, Jr., Bedford, Mass.

[73] Assignee: Cytyc Corporation, Marlborough, Mass.

[21] Appl. No.: 717,090

[22] Filed: Jun. 18, 1991

Related U.S. Application Data

[62] Division of Ser. No. 487,637, Mar. 2, 1990, abandoned.

[51] Int. Cl.[5] B01D 17/12

[52] U.S. Cl. 210/741; 210/90; 210/97; 210/808; 422/81; 422/101; 73/61.47; 436/177

[58] Field of Search ..... 604/65, 67, 406; 128/DIG. 12, DIG. 13; 210/90, 134, 808, 321.65, 741, 141, 143, 97; 422/81, 82, 101; 436/63, 177, 178; 137/14, 488; 73/61.47

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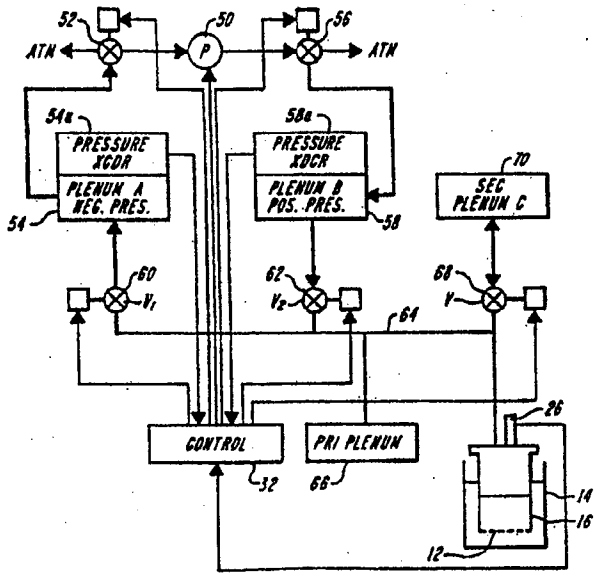
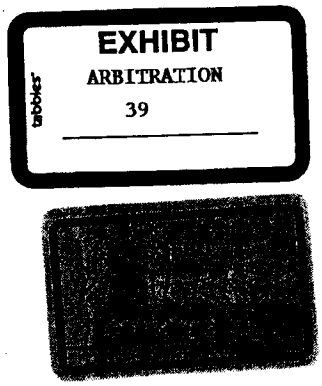
Primary Examiner—Robert A. Dawson
Assistant Examiner—Joseph Drodge
Attorney, Agent, or Firm—Lahive & Cockfield

[57] ABSTRACT

A method and apparatus for the controlled instrumentation processing of cells and other paricles with a filter device measures a parameter of the flow through the filter device of a fluid carrying the particles. A measure of the change of fluid flow through the filter device yields desired information for quantizing the particles and for quantizing the obstruction of the filter device by the particles. The method and apparatus typically operate automatically.

7 Claims, 2 Drawing Sheets





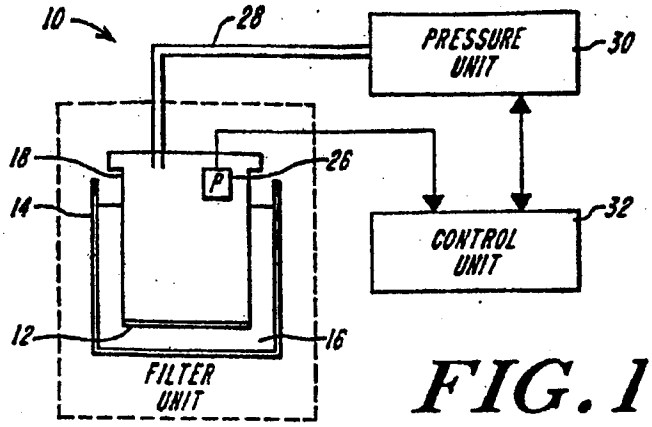


FIG. 1

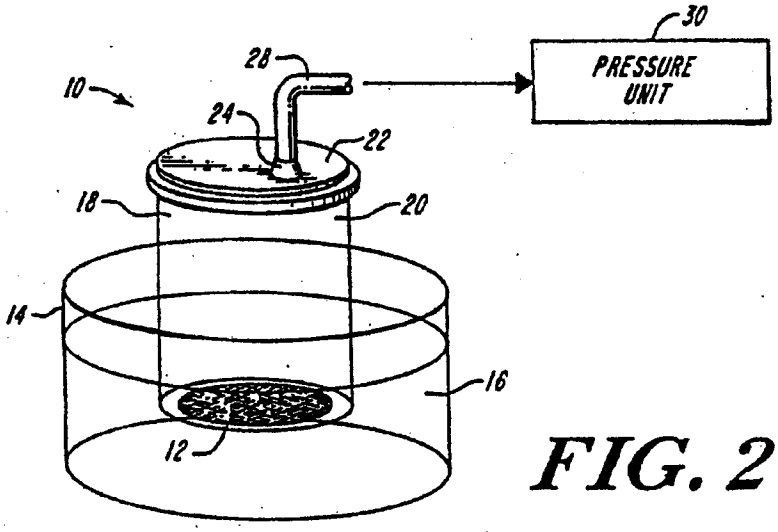


FIG. 2

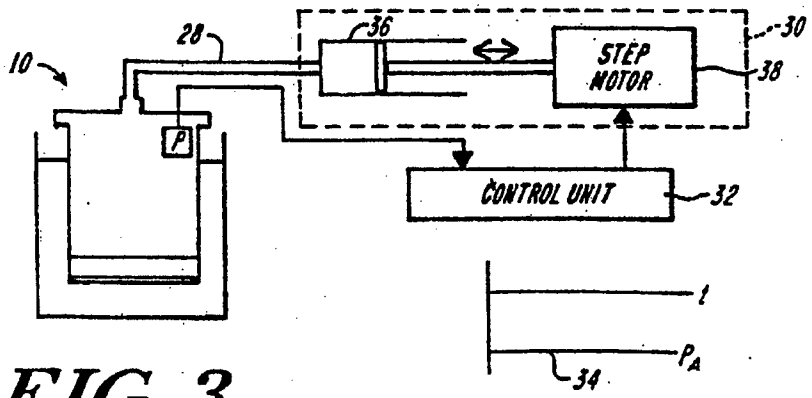


FIG. 3

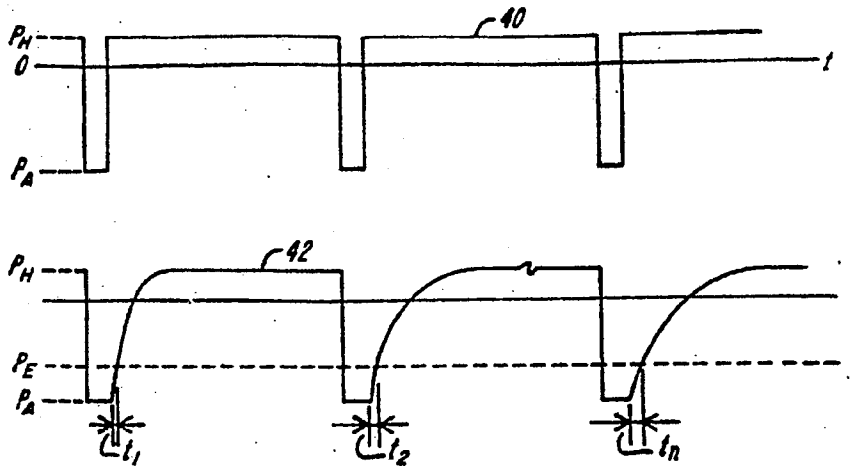

40
P_H
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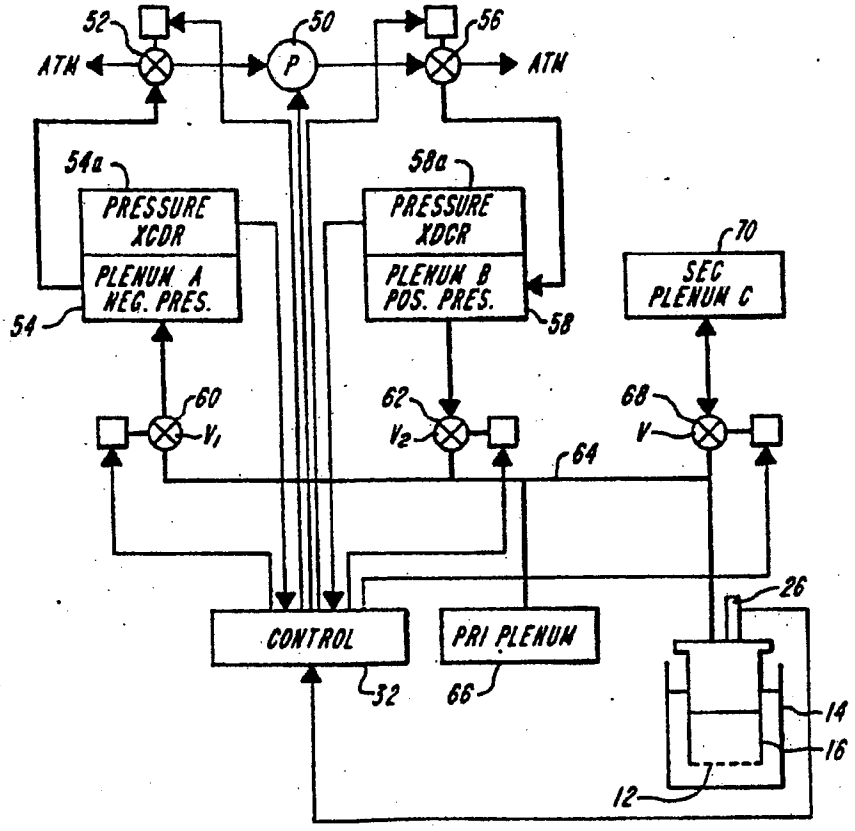
FIG. 4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PRESSURE XCDR
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PLENUM B POS. PRES.
70
SEC PLENUM C
54
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60
V_1
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V_2
68
V
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CONTROL
32
PRI PLENUM
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16
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FIG. 5

METHOD AND APPARATUS FOR CONTROL OF FLOW THROUGH A FILTER CHAMBER BY MEASURED CHAMBER EQUILIBRATION PRESSURE

This is a division of application Ser. No. 487,637, filed Mar. 2, 1990 now abandoned.

BACKGROUND

This invention relates, in one instance, to measuring the quantity or concentration of cells in a biological sample. The invention is useful in anatomic pathology, which is a medical and laboratory specialty that makes diagnoses on findings in human tissues and cells.

More broadly, the invention provides a method and apparatus for the controlled instrumented processing of particles with a filter device. The filter device is of the screen type, e.g. a membrane filter, that blocks particles larger than a threshold size and passes smaller particles. The particles of interest are carried in a fluid, and a change in the flow of the liquid carrying the particles, due to blockage of the filter device by the particles, provides information of interest both regarding the blockage of the filter and regarding the particles.

The invention thus provides quantitative instrumentation information regarding particles, generally of unknown particles, by an indirect technique that measures a flow condition of a screen-type filter device in the flow path of a fluid that carries the particles.

One application of the invention is in the pathological test, termed a Pap smear test, that examines cells for the presence of cancer. An established procedure for this test transfers a measured quantity of cells from a biological sample to a microscope slide for examination. One prior procedure for obtaining the desired measured quantity of cells from the sample employs a flow cytometer, such as a Coulter counter. Another prior cell-counting procedure employs a photometric technique in which light is directed through a fluid-suspension of the cells. Photodetectors responsive to the resultant scattered light provide signals that are a measure of the quantity of cells in the suspension.

These known cytological procedures for quantizing cells have drawbacks, including requiring expensive equipment and having limited performance in terms of reliability, repeatability, accuracy and precision. They also present biohazard risks, including from the handling of biosamples.

It is accordingly an object of this invention to provide an improved method and apparatus for quantizing cells and other particles carried in a fluid medium. Specific objects are to provide such a method and apparatus for implementation at a relatively low cost, and for controllable automated operation with relatively high reliability, repeatability, accuracy and precision.

Other objects of the invention are to provide an improved method and apparatus for collecting a selected quantity of cells and other particles that are carried in a fluid medium, particularly in a liquid medium.

It is also an object of the invention to provide an improved method and apparatus for determining a quantitative measure of the flow condition of a screen-type filter device subject to obstruction by particles larger than a known threshold size.

Another object of the invention is to provide an improved method and apparatus for collecting a specified sample of cells for cytological examination.

Other objects of the invention will in part be obvious and will in part appear hereinafter.

GENERAL DESCRIPTION

In accordance with the invention, a quantitative measure responsive to the number of particles, e.g. cells, in a fluid medium is obtained by providing a screen-type filter device in a flow path for the particle-carrying fluid. A flow condition, e.g. a selected pressure or flow velocity as a function of time, is imposed on the fluid medium. A measurement is made of a parameter responsive to the resultant flow, including change in flow, through the filter device due to the applied flow condition. The invention further provides for determining a selected change in that measured parameter responsive to the obstruction of the filter device by particles larger than a threshold size.

As used herein, a screen-type filter device refers to a filter, such as a membrane filter, that blocks cells and other particles larger than a selected threshold size and that passes smaller particles essentially without obstruction. Such a filter device typically has a filtering surface that is progressively obstructed as it blocks an increasing number of particles above the threshold size.

The applied fluid condition can be a pressure signal that causes fluid to flow through the filter device. Examples include an applied pressure signal that remains essentially constant over a selected time interval. Another example is a succession of pressure pulses, typically of known magnitude, duration and time spacing. The applied flow condition can also be an applied fluid velocity through the filter device. Examples are to maintain a selected constant flow through the filter device, over a selected time interval, and to apply a succession of flow pulses.

The measurement of a parameter responsive to flow through the filter device due to the applied flow condition includes, in one practice of the invention, measuring the rate of flow in response to an applied uniform pressure signal. In another practice, it includes measuring the change in pressure across the filter device required to maintain a selected flow velocity. Another example is to measure the time required for the flow through the filter device to change by a selected amount, typically as measured by a change in flow rate for a given applied pressure or by a change in pressure to maintain a selected flow rate.

In accordance with a further practice of the invention, the applied condition, or applied flow signal, is a succession of pulses, and the measured parameter monitors the equilibration of the flow following each applied pulse. In one illustrative instance, the measured parameter is the time for the flow velocity to equilibrate to a selected relative level following application of a selected pressure pulse.

In one specific practice of the invention, a liquid suspension of cells flows under constant applied pressure through a membrane filter. The rate of fluid flow through the filter device is measured, typically either for a selected interval of time or until the flow rate decreases by a selected amount. The change in fluid flow through the filter device is directly responsive to the number or concentration of particles or cells in the liquid, because the filter blocks the cells of interest while passing smaller cells, and accordingly becomes increasingly blocked or clogged by the cells of interest.

In another specific practice of the invention, a succession of known pressure pulses, which can be of positive

pressure or of negative pressure, is applied to drive the cell-carrying fluid through the filter device, and the time is measured after each pulse for the pressure across the filter device to return to a selected relative level, i.e. to equilibrate a selected amount.

When the measured equilibrate times have increased from the initial measure, i.e. for the initial pressure pulse, by a selected amount, a corresponding known quantity of cells has collected on the filter.

The practice of the invention thus, in one aspect, measures the flow condition of a screen type filter as it becomes increasingly obstructed, to determine a measure of particles in the fluid medium directed through the filter. The particles being measured in this indirect way have a size larger than a selected value determined by the pore size or other porosity measure of the filter screen.

The practice of the invention can thus provide a quantitative measure regarding particles in a fluid medium larger than a selected threshold value, and the measure is obtained indirectly, by applying the pressure and flow factors of Boyle's law with a screen-type filter. The quantitative measure can be of the number of particles, where the average size of the particles above the threshold value is known. Otherwise, the measure is of the relative area or portion of the filter surface that the particles cover.

The practice of invention further provides for collecting a selected quantity of cells or other particles carried in a liquid or other fluid medium. For this practice of the invention, continued flow of the fluid deposits progressively more particles above the threshold value on the filter surface. Thus an increasing area of the filter surface collects and is obstructed by additional particles. This obstruction of a known relative portion of the filter surface area corresponds directly with the collection of a known quantity of particles having a known average size larger than the threshold size. This quantitatively known collection of particles, which typically is obtained from an unknown quantity of particles in a sample liquid or other fluid, can be further processed, typically by removal of the collected particles from the filter device, or in response to a reverse pressure or reverse flow. One illustrative practice is to collect a selected quantity of cells in this manner and to subject the collected quantized cell sample to cytological examination, using known cytological testing techniques.

The invention further features a programmable control element that applies a selected flow signal for producing a flow of fluid that carries particles through the filter device, and for monitoring flow-responsive parameters, such as pressure across the filter or fluid flow through the filter. The programmable control element enables the practice of the invention to be automated, to have a controlled fluid flow or pressure change, and to stop or otherwise change the operation automatically, depending on the application.

A further feature of the invention provides an apparatus having a container for the fluid medium that carries the particles and having a vessel closed at one wall portion with a filter device that blocks passage of cells or other particles of interest. The vessel is disposed with the filter device immersed in the fluid in the container. In one specific cytological embodiment, the vessel disposes the filter device immersed below the level of a cell-carrying liquid in the container. A fluid source applies a selected flow condition to the filter device, causing the fluid medium to flow through the filter device from the container to the vessel. One or more sensors are provided for measuring one or more parameters responsive to the fluid flow through the filter device.

Another feature of the invention provides a chamber element in fluid communication with the vessel and container system for reducing the effect of changes in the height of the liquid therein.

The apparatus also has a source that applies a selected flow condition to the container-vessel system. The source can apply a selected pressure condition upon the filter device, or impose a selected fluid flow through it. In accord with a further feature of the invention, a further chamber element is provided to decrease the time for the pressure across the filter device to equilibrate after an applied pressure pulse, and thereby to speed up the overall time for measurement in accordance with the invention. This further chamber element has a volume closed to the atmosphere and greater than a volume associated with the filter vessel.

A further practice of the invention directs a flow of air carrying microscopic particles, for example, contaminants above a selected size, across a membrane filter that blocks particles of interest while passing smaller particles. When the average size of the particles above this threshold value is known, a measurement of the change of the fluid flow through the filter yields a precise and reliable measure of the quantity of the airborne particles. Further, this practice of the invention can collect a known quantity of the particles on the filter for further measurement or other processing.

The invention thus provides a method and apparatus for determining quantitative information regarding particles above threshold size, including airborne particles and biological cells, present in a fluid -- either gaseous or liquid -- indirectly, by a measurement of the fluid flow. The practice of the invention can employ relatively inexpensive measuring equipment that operates with dependability and accuracy and precision, and on a controllable automatic basis.

The invention accordingly comprises the several steps and the relation of one or more of such steps with respect to each of the others, and the apparatus embodying feature of construction, combinations of elements and arrangement of parts adapted to effect such steps, all as further exemplified in the following detailed disclosure, and the scope of the invention is indicated in the claims.

For a fuller understanding of the nature and objects of the invention, reference should be made to the following detailed description and the accompanying drawings, in which:

FIG. 1 is a schematic block diagram of particle quantizing apparatus according to one practice of the invention;

FIG. 2 shows a liquid container and filter vessel for use in the apparatus of FIG. 1;

FIG. 3 is a schematic representation of the FIG. 1 system illustrating operation with a constant applied pressure signal;

FIG. 4 shows graphs illustrating operation of the FIG. 1 system with a pulsed pressure signal; and

FIG. 5 is a block schematic representation of a pressure unit according to the invention.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS

FIG. 1 shows a system 10 according to one practice of the invention for controlled instrumented processing of biological cells. The illustrated system collects a selected quantity of cells onto a screen-type filter 12. The system 10 has a specimen container 14 that contains a liquid 16 that carries the cells. The filter 12 is on the bottom wall of a collection vessel 18. The collection vessel is fitted within the specimen container 14 to immerse the filter 12 into the liquid 16 in the container 14.

The illustrated specimen container 14, as shown in FIG. 2, is open at the top to the atmosphere and can be an open vessel such as a cup, vial, or beaker. The illustrated collection vessel 18 has a cylindrical tubular body 20 with the filter 12 spanning and closing a normally lower axial end. The body 20 of the collection vessel 18 is fitted with a cap 22 at the other, normally upper end. The screen-type filter 12 is preferably a membrane filter and hence is apertured with a uniform distribution of pores of substantially uniform size to block cells and other particles above a threshold size determined by the size of the pores, and to freely pass smaller particles. The filter has a filtering surface, illustrated as an essentially flat disc that has a surface area of known or readily determined size.

The cap 22 that closes the top of the vessel 18, together with the body 20, renders the vessel pressure tight except at the filter 12 and at a port 24 in the cap. As shown in FIG. 1, the illustrated cap 22 also mounts a pressure transducer 26 arranged for sensing the pressure within the collection vessel 18, preferably at its normally upper end.

As further shown in FIG. 1, a pressure hose 28 connects the port 24 of the collection vessel 18 to a pressure unit 30, so that the pressure unit is in fluid communication with the interior of the collection vessel. An electronic control unit 32 connects with the pressure transducer 26 to receive a pressure-responsive electrical signal, and connects with the pressure unit 30.

The pressure unit 30, typically in response to electrical control signals from the control unit 32, which can be microprocessor controlled, applies selected fluid conditions to the interior of the collection vessel 18. More particularly, the control unit 32 and pressure unit 30 operate the illustrated system 10 to collect a selected quantity of cells onto the underside of the filter 12, from a sample carried in the liquid 16 and wherein the cells have a known average size above the filter pore size, i.e. above a selected threshold size, and otherwise are of unknown quantity.

For this operation, the pressure unit 30, typically in response to signals from the control unit 32, applies a flow condition to the interior of the collection vessel 18 to create a selected flow of liquid from the specimen container to the collection vessel, by way of the filter 12. This flow of liquid carries cells to the filter, which accordingly becomes progressively covered and hence blocked by the cells. The pressure unit 30 applies the selected flow condition to the collection vessel until the filter becomes clogged by a selected amount, as determined at least in part by the pressure sensed within the vessel 18 by means of the transducer 26.

FIG. 3 illustrates one such operating sequence in which the applied pulse signal from the pressure unit 30 is a constant selected negative pressure within the collection vessel 18. The constant applied pressure across the filter 12 produces a flow of liquid 16 from the container 14 into the vessel 18, through the filter 12. The flow decreases with time, due to progressive obstruction of the filter by cells in the liquid. A measure of a parameter responsive to the change in flow rate accordingly provides a quantitative measure of the surface of the filter clogged by cells in the liquid, i.e. of the increase in filter clogging by the cells, and of the number of cells above the filter threshold size, assuming the average size of such cells is known.

For this illustrated embodiment, the pressure unit 30 can employ a displacement pump, such as a piston pump 36 driven by a stepping motor 38. The control unit 32 monitors the pressure in the collection vessel, by way of the transducer 26, and controls the stepping motor pulses required to maintain the constant applied pressure. When the timing of the stepping motor pulses slows by, for example, ten percent from the initial rate to maintain the selected applied pressure, the system 10 has collected a quantity of cells that covers ten percent of the filter surface. When the control unit terminates operation at this juncture, with a sample of cells having known average size above the filter threshold size, a correspondingly known quantity of cells is collected on the surface of the filter 12 and can if desired, be transferred from the filter to, for example, a microscope slide for image analysis either visually or by machine vision or both. The transfer of the collected cells from the filter 12 to a microscope slide can be carried out by applying a slight mechanical pressure within the vessel 18 against the filter 12, e.g. by pressing an alcohol-bearing sponge against the filter, after microscope slide is brought into contact with the filter 12, to essentially lift the cells off the filter 12 to adhere to the microscope slide. U.S. Pat. No. 4,395,493 discloses one practice of this type of transfer of cells from a filter type object to a microscope slide.

The embodiment of FIG. 3 thus operates with an applied pressure signal and measures a time parameter, i.e. the rate of stepping motor pulses, responsive to the resultant flow rate through the filter device, thereby to provide an indirect quantitative measure.

FIG. 4 illustrates operation of the FIG. 1 system 10 with a pressure source 30 and a control unit 32 arranged to apply a sequentially pulsed flow signal, illustrated by waveform 40, and to measure the time for the pressure within the vessel 18, i.e. across the filter 12, to equilibrate after each applied pulse to a selected level P_E. The FIG. 4 waveform 42 illustrates the pressure within the vessel 18 and hence across the filter 12 which the pressure sensor 26 senses.

The signal waveforms in FIG. 4 do not reveal the changes in the pressure head P_H, during this operation. The pressure head decreases during operation by a relatively small and significant amount, depending on the densities of the fluids in container 14 and in vessel 18. Accordingly, in the illustrated embodiment, the pressure head decreases as the levels of liquid 16 in the container and in the vessel change in response to each applied pressure pulse.

The FIG. 4 waveform 40 of pressure pulses which the pressure unit 30 applies to the collection vessel 18, and hence across the filter 12 since the collection container 14 is open to the atmosphere, shows that each pulse reduces the pressure within the vessel 18 from a positive pressure head value designated P_H to a selected small negative value designated P_A. Each illustrated applied pressure pulse has a negative P_A value of 0.050 psi. This

specific value, and others stated herein, are by way of example only and the invention can be practiced with other values as those skilled in the art will determine in accord with this description. The pulses repeat at a rate such that the pressure within the vessel 18, i.e. the vessel pressure, returns before each new pulse is applied to a value slightly below the value of the pressure head prior to the last applied pressure pulse.

The waveform 42 of the vessel pressure that results from the applied flow condition is normally at the P_H value, and drops to the P_A value in response to each applied pulse. After each applied pulse terminates, the vessel pressure gradually returns to the P_H value, as liquid flows from the sample container 14 through the filter 12 into the collection vessel 18. The pressure returns at an exponential rate.

The control unit 32 monitors the time, after application of an applied pressure pulse, for the vessel pressure of waveform 42 to equilibrate from the P_A value toward the P_H value to a selected equilibrate level P_E. The rate of pressure return is responsive to the degree of clogging of the filter, and accordingly gradually slows as an increasing portion of the filter surface becomes covered by and hence clogged by cells larger than the filter threshold size. The monitored equilibrate time t_1, t_2. . . . t_n therefore increases in direct proportion to the rate at which the filter clogs with cells.

The control unit 32 stops the pressure unit 30 from applying further pressure pulses when the equilibrate time has increased by a selected amount from the initial time t_1. The increase in equilibrate time is selected to correspond to a selected increase in filter obstruction, which in turn corresponds to the collection of a selected quantity of cells from the sample liquid 16 onto the filter 12. By way of example, a system as shown in FIG. 1 and operating as described with reference to FIG. 4 with pressure pulses each having a value of 0.050 pound per square inch and with a filter 12 having surface area of approximately three square centimeters, transfers in the order of fifty microliters of liquid from the sample container 14 into the filter vessel 18 with each applied pressure pulse. The system accordingly measures the cells within the liquid at essentially a liquid drop at a time, for each applied pressure pulse.

FIG. 5 shows a construction for the pressure unit 30 preferred for the foregoing pulsed operation of the system of FIG. 1 as illustrated in FIG. 4. The illustrated pressure unit construction embodies two further features, one of which diminishes measuring errors due to a change in the pressure head, i.e. a decrease in the pressure head as liquid is drawn from the sample container 14 into the filter collection vessel 18. A second feature speeds the equilibration of the vessel pressure to the P_H value, and thereby reduces the time required to attain a given collection of cells on the filter 12.

In the illustrated pressure unit, a pump 50 is connected by way of a valve 52 to maintain a selected negative pressure in a plenum 54, and is connected by way of a valve 56 to maintain a selected positive pressure in a plenum 58. A valve 60 connects the pressure in plenum 54 with the collection vessel 18, by way of a pressure line 64. A further valve 62 applies the positive pressure in plenum 58 to the pressure line 64 leading to the collection vessel 18. Each plenum 54 and 58 preferably is fitted with a pressure transducer 54*a* and 58*a*, respectively, and electrical leads connect the pump 50, each valve 52, 56, 60 and 62 and each plenum pressure transducer to control circuits within the control unit 32.

A primary auxiliary plenum 66 is coupled in communication with the pressure line 64, and a valve 68 selectively couples a secondary auxiliary plenum 70 in communication with the pressure line 64, the valve 68 is operated by the control unit.

The control unit 32 operates the pump and the valves 52 and 56 to maintain a selected negative pressure, e.g. −0.25 psi, in the plenum 54 and to maintain a selected positive pressure, e.g. +0.50 psi, in the plenum 58. The auxiliary plenum 66 is in direct communication by way of the pressure line 64 with the pressure vessel and accordingly is at the same pressure. The secondary auxiliary plenum 70 is coupled to be at the pressure of the collection vessel 18 when the valve 68 is open.

In the illustrated embodiment, the combined fluid volume of collection vessel 18, when empty of liquid, and of the pressure line 64 between the vessel 18 and the valves 60, 62 and 68 is in the order of ten cubic centimeters. The volume of each plenum 54 and 58 is typically two orders of magnitude or more larger. The volumes of the primary plenum 66 and of the secondary plenum 70 are selected to balance one another and the combined volumes of the vessel 18 and pressure lines 64, for the pulsed and equilibrate operation described further below. In the illustrated embodiment, the primary plenum 66 has a volume of approximately twenty cubic centimeters and the secondary plenum 70 has a volume of approximately 250 cubic centimeters.

One sequence for operating the system 10 of FIG. 1 as shown in FIG. 4 with the pressure unit 30 of FIG. 5 commences with opening the valve 60 to wet the filter 12 with a small volume of fluid from the sample container 14. (Unless stated otherwise, this and other operations described herein proceed with the valves 60, 62 and 68 in normally closed condition.) The valve 60 is then closed, and the valve 62 is opened to apply positive pressure to the collection vessel for driving liquid therein outward through the filter 12, to empty the collection vessel 18 and to remove any cells and other particles from the filter 12.

With the filter 12 thus wet with the liquid in the container 14 and the collection vessel and the filter cleared of fluid and of cells, the operation illustrated in FIG. 4 commences with valve 60 open for brief intervals to apply the pressure pulses P_A as shown in waveform 40. The control unit 32 continues this operation with the pressure unit and with monitoring the pressure in the collection vessel 18 to determine the equilibrate times, until the equilibrate time has increased by the selected margin relative to the initial value T_1. The control unit 32 then stops the operation, with a selected quantitative measure of cells collected on the filter 12.

More particularly, prior to applying each pressure pulse and with the filter vessel 18 at the head pressure corresponding to the difference in liquid level between the vessel 18 and the container 16, the control unit 32 opens valve 68 to allow the pressure in the secondary plenum 70 to equilibrate to that pressure head. The control unit 32 then closes the secondary plenum valve 68 and applies a pressure pulse to the filter chamber 18 by opening valve 60 and monitoring vessel pressure with the transducer 26. When the pressure transducer signal indicates that the vessel pressure has dropped from the head value, P_H, to the desired applied pressure, P_A, the control unit 32 closes valve 60.

The resultant pressure differential across the filter 18 causes liquid to flow from the container 16 into the vessel 18 and hence across the filter 12. The rate of

flow, and correspondingly the pressure difference, diminish at an exponential rate. During this time, all three valves 60, 62, and 68 are closed.

When the control unit 32 senses that the vessel pressure has dropped to the selected equilibrate level and has measured the corresponding time interval T_n, the control unit 32 opens the secondary plenum valve 68, to speed the return of the pressure vessel to the P_H value immediately prior to the last applied pressure pulse.

The volumes of the plenums 66 and 70 and of the collection vessel 18 and pressure line 64 are selected so that, when the valve 68 is opened after the filter vessel pressure has equilibrated to the P_E value, the head-pressure value stored in the secondary plenum 70—corresponding to head pressure prior to the last applied pressure pulse—brings the vessel pressure to a level close to, yet less than the head pressure. A relatively small further liquid flow across the filter 12 accordingly fully equilibrates the vessel pressure to a new, slightly lesser, head pressure.

Thus the secondary plenum 70, in essence, stores a pressure corresponding in value to the head pressure prior to the application of a pressure pulse, and speeds up return of the vessel pressure to a new, lesser head pressure corresponding to conditions after application of that pressure pulse. The illustrated system preferably avoids the condition where the stored pressure in a secondary plenum 70, upon opening a valve 68 after the vessel pressure is at the equilibrate value causes a reverse flow of liquid from the vessel 18 into the container 16. Such a reverse flow condition is considered disadvantageous for the illustrated operation and accordingly is avoided.

The primary plenum 66 is in parallel with and augments the collection vessel pressure, to minimize the effect of changes in pressure head. This plenum also is sized to match, or balance, the desired dynamic range of volume of the filter vessel 18, between conditions of being empty and conversely filled with liquid from the container 16, for the foregoing speed-up operation with the selected volume of the secondary plenum 70. Thus, the primary plenum 66 preferably has the smallest volume that, relative to the volume of the collection vessel 18 and pressure line 64, accommodates the dynamic range of filter vessel capacity change, without back flow of liquid outward from the vessel 18 through the filter 12. The ratio of volume in the secondary plenum 70 to the combined volumes of the primary plenum 66 and the collection vessel 18 and pressure line 64 is preferably in the order of approximately ten to one.

The foregoing arrangement of the pressure unit 30, as illustrated in FIG. 5, thus enables the illustrated system to have a small collection vessel 18 and to operate with relatively low sensitivity to changes in the height of liquid therein relative to the liquid height in the sample container 14. This reduction in sensitivity to changes in the pressure head enhances measuring accuracy and precision. The arrangement also allows the system to employ a compact and relatively inexpensive collection vessel 18 that may be discarded after each measurement for precluding intersample contamination.

It will thus be seen that the invention efficiently attains the objects set forth above, among those made apparent from the preceding description. It will also be understood that changes may be made in the above construction and in the foregoing sequences and operation without departing from the scope of the invention. It accordingly is intended that all matter shown in the accompanying drawings be interpreted as illustrative rather than in any limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention as described herein, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

Having described the invention, what is claimed as new and secured by Letters Patent is:

1. Apparatus for supplying a selected sequence of pressure conditions to a filter device for controlling the flow of particle-containing fluid through the filter device, said apparatus comprising

A. means forming a filter chamber having pressure port means and having a filter device forming a chamber wall thereof and having a porosity for blocking particles of selected size, said filter chamber being arranged for fluid to flow into the interior thereof through said filter device,

B. pressure source means arranged with valve means for selectively applying a source pressure to said chamber interior by way of said pressure port means, said source pressure being different from a first pressure in said filter chamber and producing a flow of fluid greater than any flow occurring during presence of said first pressure, and

C. control means arranged for sensing the chamber interior pressure and connected with said valve means, said control means being arranged for executing a cycle of successive operations including

(i) a first step of opening said valve means for applying said source pressure to said chamber interior for producing a selected fluid flow through said filter device,

(ii) a second step of closing said valve means for allowing a flow of fluid through said filter device for equilibrating the chamber pressure in a direction from said source pressure toward said first interior pressure,

(iii) a third step of measuring an equilibration time in which said chamber pressure equilibrates from said source pressure to a second chamber pressure intermediate said first pressure and said source pressure, said equilibration time corresponding to a degree of blockage of said filter device by the particles, and

(iv) repeating said first and second and third steps only in response to an equilibration time, as measured in said third step, less than a predetermined time value.

2. Apparatus according to claim 1 further comprising

A. means forming plenum means arranged with plenum valve means for selectively coupling said plenum means with said filter chamber, and

B. means for establishing in said plenum means, at least prior to the initial occurrence of said first step, a pressure for producing said first pressure in said filter chamber,

C. said control means being further arranged for executing said cycle of operations including

(i) closing said plenum valve means during said first step, said second step and said third step, and

(ii) opening said plenum valve means for coupling said plenum means with said filter chamber after said measured chamber interior pressure has reached said second chamber pressure.

3. Apparatus according to claim 2 in which said filter chamber has a first volume and in which said plenum

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means has a volume at least one order of magnitude greater than said first volume.

4. Apparatus according to claim 1 further comprising plenum means coupled in parallel with said filter chamber.

5. Apparatus according to claim 1 further comprising

A. first plenum means coupled in parallel with said filter chamber,

B. second plenum means arranged with plenum valve means for selectively coupling said second plenum means with said filter chamber, said filter chamber and said first plenum means together having a first combined volume, and said second plenum means having a volume at least one order of magnitude greater than said first combined volume, and

C. means for establishing in said second plenum means, at least prior to the initial occurrence of said first step, a pressure for producing said first pressure in said filter chamber,

D. said control means being further arranged for executing said cycle of operations including

(i) closing said plenum valve means during said first step, said second step and said third step, and

(ii) opening said plenum valve means for coupling said second plenum means with said filter chamber after said measured chamber interior pressure has reached said second chamber pressure.

6. Apparatus for measuring the occlusion of a filter device by particles contained in a fluid flowing through the filter device, said apparatus comprising

A. means forming a filter chamber having a filter device forming a chamber wall thereof and having a porosity for blocking particles of selected size, said filter chamber being arranged for fluid to flow into the interior thereof through said filter device,

B. pressure source means arranged with valve means for selectively applying a flow-producing pressure differential across said filter device, said flow-producing pressure differential being different from a first pressure differential across said filter device and producing a flow of fluid greater than any flow occurring during presence of said first pressure differential, and

C. control means arranged for sensing a pressure differential across said filter device and connected with said valve means, said control means being arranged for executing a cycle of successive operations including

(i) a first step of opening said valve means for applying said flow-producing pressure differential across said filter device for producing a selective fluid flow through said filter device,

(ii) a second step of closing said valve means for allowing a flow of fluid through said filter device for equilibrating the pressure differential in a direction from said flow-producing pressure differential toward said first pressure differential,

(iii) a third step of measuring an equilibration time in which said pressure differential equilibrates from said flow-producing pressure differential to an equilibration pressure differential intermediate said first pressure differential and said equilibration pressure differential, and

(iv) repeating said first and second and third steps only in response to an equilibration time, as measured in said third step, less than a predetermined time value.

7. A method for supplying a selected sequence of pressure conditions to a filter device for controlling the flow of particle-containing fluid through the filter device, said method comprising

A. providing a filter chamber having pressure port means and having a filter device forming a chamber wall thereof and having a porosity for blocking particles of selected size, said filter chamber being arranged for fluid to flow into the interior thereof through said filter device,

B. providing a pressure source arranged with valve means for selectively applying a source pressure to said chamber interior by way of said pressure port means, said source pressure being different from a first pressure in said filter chamber and producing a flow of fluid greater than any flow occurring during presence of said first pressure,

C. providing control means arranged for sensing the chamber interior pressure and connected with said valve means,

D. operating said control means through a cycle of successive operations including

(i) a first step of opening said valve means for applying said source pressure to said chamber interior for producing a selected fluid flows through said filter device,

(ii) a second step of closing said valve means for allowing a flow of fluid through said filter device for equilibrating the chamber pressure in a direction from said source pressure toward said first interior pressure,

(iii) a third step of measuring an equilibration time in which said chamber pressure equilibrates from said source pressure to a second chamber pressure intermediate said first pressure and said source pressure, and

(iv) repeating said first and second and third steps only in response to an equilibration time, as measured in said third step, less than a predetermined time value.

* * * * *

EXHIBIT 15

AMERICAN ARBITRATION ASSOCIATION

DEKA PRODUCTS LIMITED PARTNERSHIP, Claimant v. CYTYC CORPORATION, Respondent.	Case No. 11 Y 133 02624 03

DEKA'S POST-HEARING BRIEF

CONTAINS INFORMATION THAT HAS BEEN DESIGNATED AS CONFIDENTIAL UNDER THE PROTECTIVE ORDER

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January 21, 2004

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INTRODUCTION

Cytyc has breached its royalty obligations to DEKA. Specifically, DEKA licensed key inventions to Cytyc in exchange for quarterly royalties "equal to One Percent (1%) of the Net Sales of Products or Improvements." **Exh. 40**, CYTYC/DEKA License Agreement at § 3.01.[1] But Cytyc has not paid 1% of Net Sales. Starting in 1996, Cytyc has paid as little as 0.2% of Net Sales, up to about 0.3% of Net Sales, depending on the year. Indeed, Cytyc's CEO, Patrick J. Sullivan, admitted that Cytyc does not pay a full 1% of sales of the disposables:

> Q. But isn't it true, Mr. Sullivan, that on your cost-ratio basis, you pay .3 of a percent on the disposable sales instead of the full 1 percent that would apply to the processor?
>
> A. That is the allocation that we have used on the supply, on the filter device.

Hearing Vol. 3 at 79, *ll.* 11-16.

Cytyc has not accounted fairly for the ThinPrep sales when calculating DEKA's royalties. After sales of the ThinPrep system took off and Cytyc's founder, Stan Lapidus, had left the company, Cytyc began to chisel away at its royalty obligations. Cytyc unilaterally and without telling DEKA changed its royalty calculation method at least three times. Each change reduced DEKA's royalties at the same time that Cytyc's sales were increasing dramatically. Indeed, the chart on the next page shows how royalties at first paralleled sales, as one would expect, but then diverged starting in about 1996. One would expect that, if Cytyc were faithfully paying 1% of Net Sales, the royalties would increase proportionately with sales. They did not.

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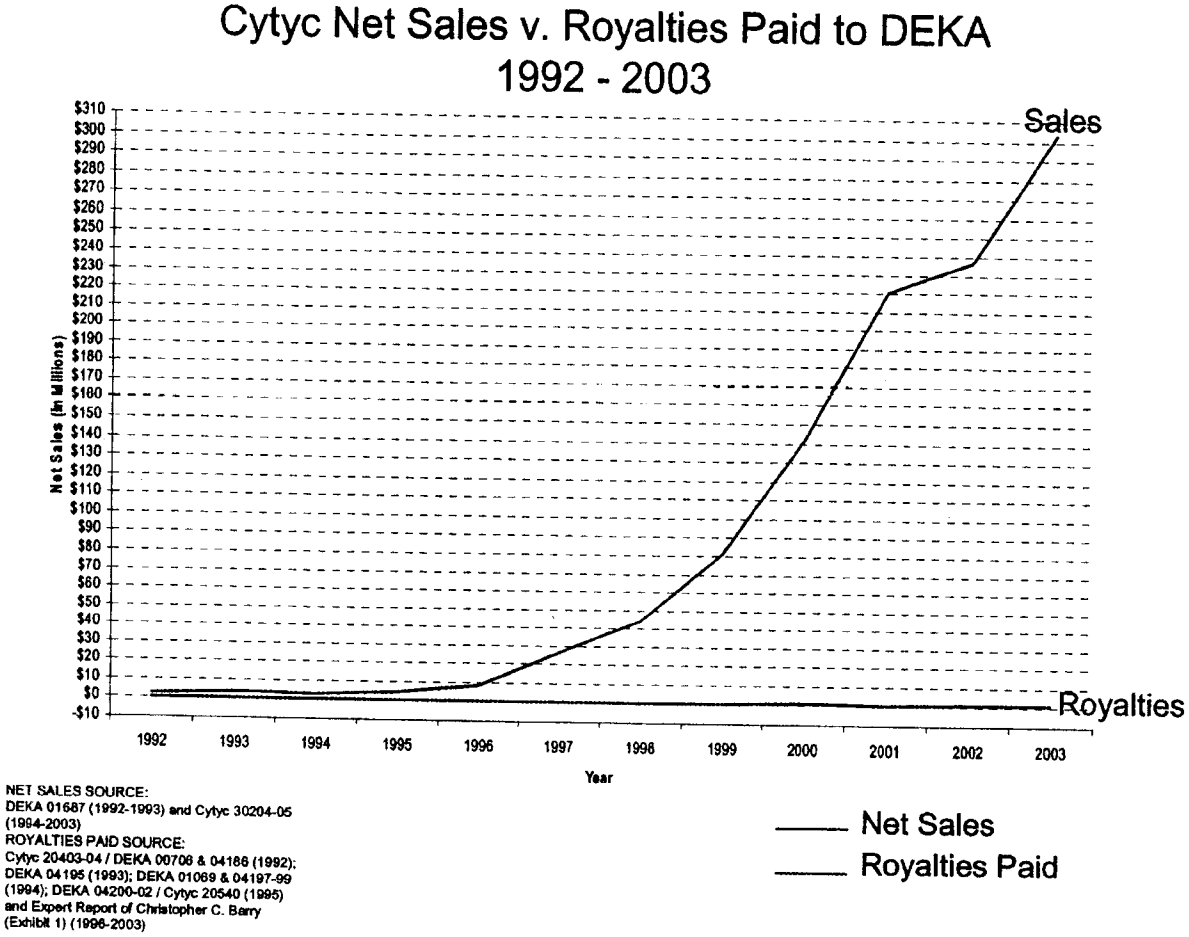
[1] All record cites in this brief can be found in the materials sent to the Panel on January 14, 2005. These materials include (1) the joint exhibits (cited by exhibit number, *e.g.*, **Exh. 15**), which are collected in three large three-ring binders; (2) the hearing transcripts (cited, for example, as "**Hearing Vol. 2** at 25, *ll.* 16-21"), which are collected in a separate binder; and (3) supplemental deposition testimony of witnesses not presented at the hearing (cited, for example, as "**Exh. A**, Lapidus depo. at 24"), which are collected in a separate, velo-bound volume.



Cytyc's words and deeds show that it has forgotten DEKA's contributions and is no longer paying DEKA a full 1% royalty. For example, when DEKA's Brendan Duffy and Charlie Grinnell challenged Cytyc on its royalty calculations, Cytyc's CFO, Bob Bowen, told them that if DEKA continued seeking to correct the royalties, he would simply change the relative pricing of certain products "to put the royalty where he thinks it's appropriate." **Exh. 102**, Charlie Grinnell's Notes of Meeting on May 21, 2002. Bowen then said that he would "manipulate" the accounting data to keep DEKA's royalty artificially low. *Id.* Indeed, Cytyc's manipulations have resulted in royalty underpayments of over $7.3 million (through June 2004) and counting.

As detailed in Section I, DEKA contributed the technology, financial assistance, and credibility instrumental to Cytyc's success. Those contributions established a fiduciary duty for Cytyc to account fairly for the royalties. Those early dealings (1989-93) also help explain the intent of the license agreement. As seen in Section II, the royalties apply to all disposables. Cytyc, however, has wrongfully limited royalties to the filter cylinder component. Moreover, Cytyc has breached the license even if the royalty applies only to filter cylinders because Cytyc has used the disposables' manufacturing costs, rather than their "Net Sales" price, to calculate royalties. Manufacturing cost is not the same as sales price. Section III details Cytyc's breach of its fiduciary duty and its unfair and deceptive acts. Section IV rebuts Cytyc's limitations, laches, and waiver defenses and shows how Cytyc prevented DEKA from discovering Cytyc's breaches.

I. DEKA'S CONTRIBUTION TO CYTYC'S SUCCESS

Cytyc's founder, Stan Lapidus, credits DEKA's technical and financial contributions with giving life itself to Cytyc. To Lapidus, DEKA's contributions were valuable for two reasons:

> Reason one is, I had no idea how to implement the thing [the slide preparation system], the invention of sucking cells against a filter and measuring the differentials in concentration. And I had no credibility with investors and I was in fund-raising mode. And so Dean's credibility as a gizmo guy . . . was instrumental in raising the Series A money.

Exh. A, Lapidus depo. at 39, *ll.* 11-18.

DEKA developed the ThinPrep slide preparation system and helped Cytyc raise venture capital. DEKA's good name allowed Cytyc to raise $5 million in initial investments. DEKA's know-how was "essential" for implementing what became the ThinPrep system. *Id.* at 39-40.

Lapidus rates DEKA's contributions as "extremely important" and "invaluable." *Id.* at 96-97. Even Cytyc's expert, Professor Cockburn, agreed that DEKA's contributions were important. **Hearing Vol. 3** at 155-156.

As Cytyc's CEO and Chairman, Mr. Sullivan, testified, "a large part of [Cytyc's] success is due to the success of the ThinPrep Pap Test." **Hearing Vol. 3** at 75, *ll.* 16-21. In 2003 alone, the ThinPrep system accounted for 97% of all Cytyc sales. **Exh. D**, Levitz depo. at 124-125. Mr. Sullivan estimated that the current domestic sales of ThinPrep products are about $260 million annually ($250 million for disposables plus $8-10 million for processors). And that figure does not include international and non-gyn disposable sales, which also fall within the license agreement. **Hearing Vol. 3** at 76-77.

Without DEKA's technical and financial contributions, however, there would be no ThinPrep system, no $260 million in annual domestic sales, and likely no Cytyc.

As both Dean Kamen and Stan Lapidus tell the story, they were friends and knew of each other's engineering achievements. In the fall of 1988, Lapidus visited Kamen to seek his help with a problem. Lapidus explained that he had started a company, Cytyc, to build machine vision (*i.e.*, computer imaging) equipment to read Pap smear slides. But to make the machine vision work, Lapidus needed a way to prepare better sample slides having a thin layer of cells rather than the clumps of cells, blood, and mucus that would otherwise obscure the sample if the slide were prepared in the conventional way, by hand.[2] Lapidus had failed to solve that problem. Believing, however, that DEKA had the necessary expertise, Lapidus asked Kamen if he could solve the problem. **Hearing Vol. 1** at 83-91; **Exh. A**, Lapidus depo. at 10, *ll.* 20-22 and 13-17.

Kamen responded, "You're right. I do know how to solve this problem." **Hearing Vol. 1** at 90, *ll.* 23-24. And he proceeded to tell Lapidus about DEKA's patented FMS technology

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[2] As Lapidus explained, Pap smear slides prepared by hand are often obscured by blood or mucus. Moreover, the cervical cells are smeared onto the slide in clumps, rather than in a uniform thin layer. A lab technician can use his or her judgment to sift through the debris and clumps to spot cancerous cells. But machine vision cannot use human judgment.

and his idea for how FMS could enable a slide preparation system. As it turned out, DEKA had just finished building an infiltration monitor, which is a medical device that uses FMS to detect whether an intravenous needle is correctly inserted into a vein. DEKA had spent two years developing that device. And during that first meeting, Kamen showed Lapidus an infiltration monitor that was sitting in DEKA's machine shop. Kamen told Lapidus that he could adapt that infiltration monitor into a slide preparation machine. (The infiltration monitor uses FMS to sense clogging of a needle. Kamen envisioned that the slide preparation machine would likewise use FMS to sense clogging of the filter pores by the desired cervical cells.) Lapidus loved Kamen's idea and asked Kamen to develop and build a slide preparation machine for Cytyc. Kamen accepted the challenge. **Hearing Vol. 1** at 91-95; **Exh. A**, Lapidus depo. at 16-17.[3]

The next step for Kamen and Lapidus was to forge a business relationship. First, Kamen explained to Lapidus DEKA's typical business model, in which (a) the client covers DEKA's costs in developing the requested product; (b) DEKA keeps patents on the technology it develops but licenses that technology to the client in a specific field of use; and (c) DEKA receives royalties on sales of the resulting product. Under this model, DEKA becomes a partner of the client and shares in its success or failure. *See* **Hearing Vol. 1** at 74-78 and at 96 ("I told him [Lapidus] how we do business with everyone else"); **Exh. A**, Lapidus depo. at 27, *ll.* 6-18 (Lapidus recalls that Kamen explained the business model).

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[3] FMS stands for "Fluid Management System" and involves, for example, measuring changes in pressure or volume of a flowing liquid and using those measurements to control the flow of the liquid through a line. In lay terms, FMS is a sophisticated and very sensitive pumping technology for controlling or measuring fluid flow. By the time that Lapidus and Kamen met in 1988, DEKA had applied FMS to a variety of medical devices, had licensed inventions relying on FMS to large medical product companies like Baxter Healthcare, and had filed or received several patents for embodiments of FMS technology. **Hearing Vol. 1** at 97-100 (explaining FMS technology); **Exhs. 217, 219, 240,** and **242** (examples of FMS patents).

Kamen then told Lapidus that, in keeping with DEKA's business model, "I don't want to make a profit certainly from you, Stan. I want a piece of [Cytyc's] success if this thing works. And you've just got to cover my cost." **Hearing Vol. 1** at 96, *ll.* 7-9. Kamen estimated that his cost to develop and build a prototype would be a few hundred thousand dollars. *Id.* at *ll.* 13-15.

Lapidus told Kamen that Cytyc had no money and could not even cover DEKA's costs. **Hearing Vol. 1** at 96, *ll.* 16-20; **Exh. A**, Lapidus depo. at 18-19. At this stage in 1988 or early 1989, Cytyc was a start-up company, with no product, no revenue, and just two employees. **Exh. A**, Lapidus depo. at 15, *ll.* 5-9 and 28, *ll.* 1-7. Cytyc needed to obtain financing before it could hire its own engineers or even rent office space. *See* **Exh. 139**, Cytyc's 1989 Operations Plan at 30591 ("We will bring the initial development team on board upon conclusion of the financing" and "Upon conclusion of the financing we will set up our physical plant"). In effect, DEKA would act as Cytyc's R&D lab, engineering team, and machine shop all rolled into one.

Eventually, DEKA made important concessions, deviating from its business model so that Cytyc could survive and prosper. After all, as Kamen testified, he wasn't dealing with a giant company--he was dealing with Stan, his friend. **Hearing Vol. 1** at 126, *ll.* 15-16. Thus, they agreed that Cytyc would pay just 50% of DEKA's costs and that Kamen would subsidize the rest. Nor would DEKA bill Cytyc until after Cytyc had raised money. *Id.* at 96-97 and 128, *ll.* 9-14; **Exh. A**, Lapidus depo. at 18-19. Moreover, Cytyc would pay only a 1% royalty, far less than the 3-5% royalty DEKA usually receives in the medical device field. *Id.*; *see also* **Hearing Vol. 1** at 82-83 (Cytyc agreement is the only time DEKA ever agreed to 1%).[4]

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[4] DEKA agreed to this low rate because it expected that Imager sales would increase sales of the ThinPrep sytem. But Cytyc never got FDA approval for the Imager until 2003 and DEKA had to wait years for increased royalties. **Hearing Vol. 1** at 151. DEKA was also supposed to get 1% of the whole company, but Cytyc later diluted that equity nearly 14 times, *Id.* at 131-32, further depriving DEKA of its bargained-for compensation for solving Cytyc's problem.

Lapidus also asked Kamen to assign to him patents resulting from the work, explaining that Cytyc needed the patent rights to raise money from its investors and to be able to prosecute any infringers. Even though DEKA normally retains all of its own patents, Kamen relented for his friend's sake. **Hearing Vol. 1** at 125-126; **Exh. A**, Lapidus depo. at 98, *ll.* 7-18.

Finally, Lapidus gave DEKA an equity stake in Cytyc. **Exh. A,** Lapidus depo. at 24-25. According to Lapidus, the purpose of the equity stake was to ensure that DEKA would share in the success of the whole company, not just the success of the ThinPrep system. *Id.* In other words, Lapidus acknowledged that DEKA had contributed to the birth of Cytyc.

Over the next year, DEKA undertook and accomplished the following development efforts, as outlined in Cytyc's 1989 Operations Plan: "Disposable design," "Disposable tooling," "Machine mechanism design," "Machine packaging design," "Design [of] analog and digital control electronics," "Build prototype," and "Build Beta Units." **Exh. 139** at p. 30593; *see also* **Hearing Vol. 1** at 104-105; 115, *ll.* 4-7 ("we certainly did all of those things"); and 251 ("We built the whole machine that they [the disposables] go in").

DEKA's work on the slide preparation system freed Cytyc, with its limited resources, to work on what was then its main focus--the Imager. As Kamen testified, "Stan was working on his Imager; I was working on the cell prep issue." *Id.* at 120, *ll.* 13-14.

Cytyc's former engineering manager, Hugh Vartanian, also noted that while DEKA developed the slide preparation machine and filter cylinders, he focused on the Imager. He also confirmed that DEKA did, in fact, design and build prototypes of the ThinPrep system. **Exh. E**, Vartanian depo. at 37-42, 46, 59-60, and 65-67; *see also* **Exh. 29**, Vartanian Engineering Notebook at pp. 28769, 28772, 28778, 28783, 28799, and 28801 (noting DEKA's efforts and contributions by DEKA engineers Jerry Norman, Bob Bryant, and Rick Villeneuve).

One of DEKA's assigned goals was to lower the manufacturing and material cost of the disposables. See **Exh. 139**, 1989 Operations Plan at 30593 ("An important goal for the prep machine is to keep disposable costs down . . . we are beginning to feel comfortable with disposable cost, based on experimental results at DEKA") (emphasis added). Kamen recalled that DEKA worked very hard to lower the cost. **Hearing Vol. 1** at 109-110. DEKA normally gets a bonus for reducing its clients' costs and would never expect to be penalized for designing low cost solutions. *Id.* at 199, *ll.* 4-15. As explained in Section II, however, DEKA is penalized because Cytyc uses the low manufacturing cost of the disposables to reduce DEKA's royalties.

DEKA successfully delivered prototypes of the ThinPrep system, proving to Cytyc's investors that the system would work. **Hearing Vol. 1** at 132-134; **Exh. A**, Lapidus depo. at 22 and 39-40. DEKA also wrote software for controlling the slide preparation machinery. **Hearing Vol. 1** at 114-117; *see also* **Exh. 33**, Cytyc Memo at 30318 ("DEKA Research and Development Corp. . . . developed software for automation of the slide transfer process"); **Exh. 35** (copy of DEKA's original computer source code). DEKA's engineers spent months on the ThinPrep project. *See* **Exh. 133-134**. (DEKA invoices and time sheets for the project).

One of DEKA's main contributions, of course, was its FMS, which Cytyc touts as the "key" component of the ThinPrep system. Indeed, ThinPrep depends on, and would not work without, FMS. *See* **Exh. E**, Vartanian depo. at 114-115; **Exh. 30**, Cytyc Memo at 28729 (describing FMS "as a key component of the ThinPrep Processor") (emphasis added).

The resulting ThinPrep system consists of (a) the processor and (b) the four disposables--*i.e.*, filter cylinder, vial of preservative solution, microscope slide, and collection device. The ThinPrep system, which is used to place a thin layer of cells on the slide (*i.e.*, "prepare the slide"), should be contrasted with the Imager, which is the "machine vision" equipment that

automatically reads the slide and identifies areas of interest for the lab technician. As explained above, developing the Imager was the original focus of Cytyc's business plan. To work properly, however, the Imager needs a specially prepared slide. And that is where DEKA came in. DEKA developed the slide preparation system (ThinPrep) that enables the Imager to work. [5]

II. CYTYC BREACHES THE LICENSE AGREEMENT

The license agreement requires Cytyc to pay DEKA a royalty "equal to One Percent (1%) of the Net Sales of Products or Improvements." **Exh. 40**, License Agreement at § 3.01. But Cytyc does not base the royalty on "Net Sales." Nor does it pay the required 1%. Cytyc pays only about a third of 1% and calculates the royalty based on cost---*i.e.*, what it costs Cytyc to manufacture the product--not on the sales price paid by the customer, as the agreement requires.

The term "Products" includes "Product Hardware" and "Product Disposables." *See* **Exh. 40**, License Agreement at § 1.01 (g). Cytyc contends that "Product Disposables" means only filter cylinders. Cytyc then compounds that error by using a royalty calculation method of its own invention ("cost ratio" apportionment), which DEKA never authorized, to calculate royalties due on filter cylinders sold in multi-component kits. Instead, as argued in Subsection A, Cytyc should have paid royalties on all disposables used to prepare slides, not just on filter cylinders. As argued in Subsection B, even if the royalty applies only to filter cylinders, Cytyc bases royalties on the filter's manufacturing cost, not on the required "Net Sales" price paid by Cytyc's customers, and thus breaches the agreement. Indeed, when Cytyc sells filter cylinders separately, Cytyc pays 1% on the actual "Net Sales" price, as required, not on manufacturing

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[5] Cytyc sells the four ThinPrep disposables in various configurations. The most common configuration is the 4-part "ThinPrep Pap Test" kit. But Cytyc also sells each of the disposables separately. Cytyc's price lists (**Exhs. 11, 12**, and **120**) list various ThinPrep product offerings. The Cytyc product catalog (**Exh. 135**) pictures these products.

cost ratios. Thus, it was possible all along for Cytyc to calculate royalties based on "Net Sales," and Cytyc did not need to contrive its cost ratio method. It did so, however, to reduce royalties.

Cytyc's breaches have resulted in an underpayment of $7.3 million (through June 2004) and counting. Also, as seen in Subsection C, Cytyc owes over $155,000 for the KPMG audit.

A. CYTYC OWES ROYALTIES ON ALL DISPOSABLES

1. 'Product Disposables' Includes All Four Disposables

Under the license agreement, the royalty applies to "Net Sales of Products or Improvements." **Exh. 40**, License Agreement at § 3.01. The term "Products" includes both "Product Hardware" and "Product Disposables." *Id.* at § 1.01(i). Of note, the definition of "Products" does not read, for example, "Product Hardware and *filter cylinders*." Rather, the term uses the broader, generic "Disposables," showing that the term includes more than filter cylinders and does not exclude other components. Indeed, "Product Disposables" includes not just filter cylinders but also any "similar disposable provided such disposable utilizes the Cytyc Technology, the FMS Technology or both." License Agreement at § 1.01(g) (emphasis added).

In other words, if a disposable utilizes FMS Technology and/or Cytyc Technology in the slide making process, it qualifies as a "similar disposable." That reading is in keeping with Dean Kamen's understanding. To him, disposables that use either FMS or Cytyc Technology are "[w]hatever it takes to make a slide." **Hearing Vol. 1** at 135, *ll.* 12-15 (emphasis added).

Both FMS and Cytyc Technology are defined in the agreement. The FMS Technology, of course, is the "pre-existing fluid pumping and control technology" (*see* "Recitals"), along with all improvements, know-how, trade secrets, embodiments, designs, and other intellectual property, all as defined in § 1.01(c). FMS is the "key component" of the ThinPrep System, as Cytyc's Vartanian admits. **Exh. E**, Vartanian depo. at 114-115. The Cytyc Technology, as

broadly defined in § 1.01(a), includes all of the work, know-how, formulae, trade secrets, and other intellectual property reflected in the '084 patent (**Exh. 39**), all related patents, and all technologies "that pertain to it." Certainly, the other disposables, including the vials of solution, are products of FMS and/or Cytyc Technology and are used to make slides.[6]

Indeed, FMS is a fluid pumping and control technology. The only fluid that the ThinPrep system pumps is the preservative solution containing the cell sample. So naturally, the vial of solution is, under § 1.01(g), a "disposable [that] utilizes the Cytyc Technology, the FMS Technology or both." The inventor of FMS Technology, Dean Kamen, "can't imagine how you use FMS, Fluid Management System, without fluid. How do you make a slide without the sample? I believe that's obviously an important piece of it." **Hearing Vol. 1** at 136, *ll.* 2-13.

DEKA's technology licensing expert, Mr. Goldscheider, agrees:

> The words "similar disposables" are crucial in this case. They've been mentioned by the attorneys; they've been mentioned by the witnesses. And if one understands the concept of this patented FMS Technology system, together with the Cytyc Technology, one realizes that if a component is affected by either FMS or Cytyc Technologies, then it becomes a disposable, if it's part of this unit. It doesn't have to look like a filter. It doesn't have to look like a cylinder. It can look like a collection device or the other things as well.

Hearing Vol. 2 at 270, *ll.* 3-14.

"Similar disposables" cannot mean new versions of filter cylinders or new components that replace the function of filter cylinders, as Cytyc has argued. That is what the term "Improvements" covers. That term is broadly defined in § 1.01(d) to mean modifications, alterations, and the like that "perform the same or a substantially similar purpose as the Products." The royalty is due on "Products or Improvements," so it would be redundant to

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[6] The term "Cytyc Technology" is somewhat misleading because DEKA's Kamen and Villeneuve are joint inventors of Cytyc Technology, including for example the '084 patent. *See* **Exh. 39**, "084 Patent.

define "similar disposables" as just an improved filter cylinder. Similar disposables, therefore, must mean any other component, in addition to the filter cylinder, that utilizes FMS Technology, Cytyc Technology, or both, to make a slide. Mr. Kamen agrees. *See* **Hearing Vol. 1** at 211, *ll.* 2-21 ("Well, it's certainly similar if you're using it to make a slide").

2. Parol Evidence Cannot Be Read into the Final Agreement

Cytyc points to correspondence from 1990 and 1991--two and three years before the license agreement was finalized--for the proposition that vials of preservative solution are excluded from the royalty. For example, a May 1990 letter between Kamen and Lapidus states "Vials filled with collection medium are explicitly excluded from this Agreement." **Exh. 79.**

But that term does not appear in the final agreement. And importantly, the agreement contains an integration clause, entitled "Entire Agreement," stating that the agreement "constitutes the entire understanding of the parties . . . and supersedes all prior understandings and writings relating thereto." **Exh. 40**, License Agreement at § 13.5 (emphasis added).

Under New Hampshire law, which governs the agreement (*see* § 13.3), a contract with an integration clause is complete, absent strong evidence to the contrary. Parol evidence cannot be used to contradict the plain meaning of a disputed clause or to add a term not present in, or deleted from earlier drafts of, the integrated contract. *See, e.g., Richey v. Leighton*, 632 A.2d 1215, 1216-17 (N.H. 1993). Cytyc has offered no evidence that the agreement is incomplete. Thus, Cytyc cannot use the May 1990 letter and similar correspondence to add a new term--that vials of solution are excluded--to the final license agreement, which does not contain that term.

3. The Negotiations Show that the Royalty Applies to All Disposables

If the Panel considers parol evidence, it must consider the negotiations in the years after the May 1990 letter. The contract negotiations closer in time to the finalization of the agreement

show that expectations changed since Lapidus originally proposed that vials of solution be excluded from the license. The evidence shows that the royalty should be based on the entire sales price of all components used to make a slide, including the vials of solution.

Specifically, in October 1991, DEKA's attorney, Stephen Hazard, wrote to Lapidus with the concern that the proprietary products could be bundled with unrelated items and that, therefore, "it may be difficult to determine how the different pieces of the unit are priced." **Exh. 86,** Letter of October 14, 1991. Hazard thus suggested an "Agreed Sales Price" concept or an alternative "percentage of total disposable sales" approach for determining the royalties. *Id.* The draft agreement accompanying this letter deletes the previous "Net Sales" clause of § 3.01 and adds a new "Agreed Sales Price" clause. *See* **Exh. 86**, draft license agreement at D 02472.

Cytyc never suggested alternative ways to solve Hazard's concern. The final agreement certainly does not specify an apportionment method, let alone cost ratio apportionment. Indeed, Lapidus said that he would never have agreed to Hazard's suggested approach because it would be "unfair to Cytyc or unfair to Dean." **Exh. A**, Lapidus depo. at 73, *ll.* 5-17 (emphasis added).

The parties apparently decided that the royalties would be paid on total sales, without apportionment, because the next correspondence restores the "Net Sales" concept removed from the October 14th draft. Specifically, in a cover letter dated two weeks later, Hazard makes clear that "we have retained the "Net Sales" concept." **Exh. 87**, letter from Attorney Hazard to Lapidus, dated October 31, 1991. The accompanying draft agreement contains a definition of "Net Sales," § 1.01(e), resembling the one in the final agreement (*i.e.*, based on the "gross sales price") and contains a royalty clause, § 3.01, that is identical to the one in the final agreement. *See Id.* at pp. 2 and 4 of draft agreement. The brief flirtation with apportionment was over.

There is no other mention in the record of apportioning sales. And there is certainly no mention in the negotiations or elsewhere of using cost ratio to do so. This record allows only two conclusions. First, the parties briefly considered but then rejected the notion that there is any fair way to carve up total sales. Instead, the parties agreed that sales would not be carved up, that royalties would be based simply on all disposables. Second, Cytyc gave up on its former proposal to exclude vials of solution from the royalty base. Cytyc did not insist on an express exclusion in the final license agreement, as it had in the earlier correspondence.

Contract law requires these conclusions. A party like Cytyc who desires a particular interpretation (in this case, that vials of solution are excluded) but remains silent, or who receives a suggestion to solve a potential problem (*i.e.*, how to calculate royalties on bundled goods) but then rejects it, bears the risk of doing so. *See, e.g., Accusoft Corp. v. Palo*, 237 F.3d 31, 42 (1st Cir. 2001) (defendant took risk that its unspoken understanding of agreement was incorrect); *M&M Transp. Co. v. Schuster Express, Inc.*, 13 B.R. 861, 872 (Bankr. S.D.N.Y. 1981) (defendant bore risk because it knew of the contingency and could have crafted a provision to address it). Cytyc's failure to address these issues in the final agreement cannot give it the right to later contrive a calculation method, never before discussed, without first consulting DEKA.

4. The Parties' Dealings Show that Royalties Apply to All Disposables

The parties' dealings after the October 1991 correspondence between Attorney Hazard and Lapidus further prove that all disposables are to be included in the royalty calculation. For example, in January 1992, Cytyc paid DEKA its first royalties. The accompanying royalty schedule shows that Cytyc paid royalties on "Disposables (Total)." **Exh. 176** at 20407. This royalty schedule discloses no use of apportionment. The royalty was not applied to only a percentage of disposables. Indeed, the schedule confirms that the royalty applied to "Total"

disposables. There is certainly no indication that cost ratio was used. Cytyc was selling the preservative solution then (*see* **Exh. A**, Lapidus depo. at 75, *ll.* 10-12), so it follows that this royalty was paid on the solution as well. Even Mr. Sullivan could not rule out the possibility that this 1992 royalty included the solution. *See* **Hearing Vol. 3** at 92, *ll.* 13-18 and 95, *ll.* 15-20. In other words, the royalty base included "Total" sales of all disposables used to make a slide.

5. The Entire Market Value Rule Requires Royalties on All Disposables

Prof. Cockburn testified that the individual component parts are "largely irrelevant. What matters is the price of the entire kit." **Hearing Vol. 3** at 111, *ll.* 17-18. If that is the case, then the royalty should apply to the price of the entire 4-part test kit and to all four disposables, even if the filter cylinder is the only proprietary component.

a. The Disposables Are Part of One Functional Unit

The Entire Market Value Rule provides that when royalty-bearing and other components are bundled, sold, or used together such that they form a "functional unit," the patentee or licensor is entitled to a reasonable royalty based on the entire functional unit and not just on the royalty-bearing component alone. *See, e.g., Rite-Hite Corp. v. Kelly Co.*, 56 F.3d 1538, 1549-50 (Fed. Cir. 1995); *see also Juicy Whip, Inc. v. Orange Bang, Inc.*, 382 F.3d 1367, 1371-74 (Fed. Cir. 2004) (infringing soft drink dispenser functioned with non-infringing syrup to achieve the end result and thus damages would include syrup sales).

Put another way, the test is whether the unit works absent the royalty-bearing component. *Kori Corp. v. Wilco Marsh Buggies and Draglines, Inc.*, 761 F.2d 649, 656 (Fed.Cir. 1985). *See also State Indus., Inc. v. Mor-Flo Indus. Inc.*, 883 F.2d 1573, 1580 (Fed. Cir. 1989) (applying Rule because "no components can be used separately, except as spare and repair parts").

The ThinPrep processor and all four disposables are certainly part of one system, one functional unit. As even Cytyc's expert, Prof. Cockburn admits, the ThinPrep processor cannot work without the filter or, indeed, without FMS Technology:

> Q. The ThinPrep System cannot work without a filter cylinder; is that right?
>
> A. That's my understanding.

Hearing Vol. 3 at 156, *ll.* 10-12. *See also* **Exh. B**, Bowen depo at 68, *ll.* 2-10 ("The ThinPrep Pap Test cannot be performed in the absence of any of these components"); **Exh. D**, Levitz depo. at 78, *ll.* 18-24 ("The product can't be used separately. All four parts are required for a test"); **Exh. E**, Vartanian depo. at 9, *ll.* 20-23 (the processor and all disposables are part of one system).

DEKA's noted technology licensing expert, Robert Goldscheider, testified that the ThinPrep processor and four disposables work as a system dependent on FMS Technology and that, therefore, the royalty should apply to the entire test kit, to all four disposables:

> FMS Technology is a system; it is not a specific product. It is the operation of a system on certain components. In this particular situation the components are the four units that were approved by the FDA: the filter, the collection device, the vial and the slide. And it is the operation of the FMS Technology, in conjunction with these units, which Mr. Sullivan tells us in his deposition are worthless by themselves, but when put together and governed by this patented system, the FMS Technology, it becomes enormously valuable.

Hearing Vol. 2 at 268-269; *see also Id.* at 280-282; **Exh. 126**, Expert Report of Robert Goldscheider at 24-26.[7]

Moreover, as Cytyc itself argues, and as Mr. Sullivan reiterated, all four components are needed to complete a ThinPrep test, and the results cannot be guaranteed if substitutes are used.

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[7] Mr. Goldscheider is a respected expert in the licensing field. Even Prof. Cockburn had to admire Goldscheider's experience and reputation as a "leading" member of the Licensing Executive Society and author of the so-called 25% Rule. *See* **Hearing Vol. 3** at 131-132.

Hearing Vol. 3 at 28, *ll.* 3-10 and at 37, *ll.* 2-8. That is all the more reason to apply the Rule. *Cf. Kalman v. Berlyn Corp.*, 914 F.2d 1473, 1477 (Fed. Cir. 1991) (unpatented filters would be included in royalties because they were "specifically designed for use with the [patented] Autoscreen and the Autoscreen is not guaranteed without the use of the special filter material").

From an economics perspective, according to Prof. Cockburn, the value, and hence the "Net Sales" price, lies in the entire kit. And that price cannot be divided, parsed, or apportioned:

> Q. And the value of the overall ThinPrep test is in the bundle of components, not in the individual components, right?
>
> A. Right.

Hearing Vol. 3 at 157, *ll.* 1-4.

When the Panel questioned Mr. Sullivan on this proposition, he agreed:

> CHAIRMAN MILONAS: So when you charge a nickel for a part or a dime for a part, if that's what it costs you to make, it's almost irrelevant. It's what the whole system does together that has great value in the market.
>
> THE WITNESS: That's correct, Your Honor.

Hearing Vol. 3 at 101-102.

Accordingly, Mr. Barry concluded that the royalty should apply to all sales of disposables. Mr. Barry understood from his work in other cases that when the parts function as a unit, the Entire Market Value Rule should apply. **Hearing Vol. 2** at 175-77, 195. And Mr. Barry further understood that situation to apply here--that all the components work together:

> Q. What enables Cytyc to sell those disposables?
>
> A. The fact there they're going to work with the equipment, the processor that's been given.

Hearing Vol. 2 at 251, *ll.* 9-12; *see also id.* at 177, *ll.* 4-7.

As Lapidus said, the 1% royalty should apply to "sales attributable to the FMS technology." **Exh. A**, Lapidus depo. at 19, *ll.* 18-22. All sales of ThinPrep products are directly attributable to FMS. Without FMS, there would be no processors and thus no need for disposables. As Vartanian testified, the processor and all disposables are part of one system. **Exh. E**, Vartanian depo. at 9, *ll.* 20-23. Thus all sales must be included in the royalty base.

b. The Entire Market Value Rule Applies to this Contract Case

Although the Entire Market Value Rule is known from patent cases, it has long been applied in breach of license and other contract matters. *See, e.g., Schaefer Fan Co. v. J&D Mfg.*, 265 F.3d 1282, 1290 (Fed. Cir. 2001) (affirming award of contract damages based on defendant's profits from the entire functional unit, not just the licensed part); *Allen Archery, Inc. v. Precision Shooting Equip., Inc.* 865 F.2d 896, 900 (7th Cir. 1989) (licensor was entitled to a royalty based on the sales of the entire crossbow, not merely the licensed component, even though that component was separable); *Avant, Inc. v. Tech Ridge, Inc.*, 355 N.E.2d 479, 481-82 (Mass. App. Ct. 1976) (commission applied to sales price of the entire system rather than to that portion of the sales price attributable to components invented by licensor); *Richards v. Liquid Controls Corp.*, 325 N.E.2d 775, 780 (Ill. App. 1975) (disputed license agreement indicated that the licensee intended to sell a complete device and so the royalty should be based on that device, not just on the licensed part); *Eno v. Prime Mfg. Co.*, 50 N.E.2d 401, 406 (Mass. 1943) (license would not be restricted to licensor's process because the process and licensee's machine "complemented each other and together constituted the means [for making the end product]").

Accordingly, the principles of the Entire Market Value Rule can be, and frequently have been, applied in the contract realm. Indeed, there is strong support for applying it here based on the course of the negotiations resulting in the final agreement, as seen in Subsections 3-4 above.

c. The Entire Market Value Rule Applies When It Is Difficult to Break Out Individual Prices

Application of the Entire Market Value Rule is particularly apt when, as in this case, the wrong-doer makes it difficult through its own accounting or sales practices to break out the price of the royalty-bearing component from the bundle of all components. *Nickerson Indus., Inc. v. Rol Mfg. Co.*, 847 F.2d 795, 799 (Fed. Cir. 1988) ("We agree that where it is 'impossible to make a mathematical or approximate apportionment' between infringing and non-infringing items, the infringer must bear the burden and the entire risk"); *TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895, 900 (Fed. Cir. 1986) (applying Entire Market Value Rule because "any adverse consequences must rest on the infringer when the inability to ascertain lost profits is due to the infringer's own failure to keep accurate or complete records"); *Eolas Technologies Inc. v. Microsoft Corp.*, No. 99-C-0626, 2004 WL 170334 at * 2 (N.D. Ill., Jan. 15, 2004) ("the bundling [of components] makes it very difficult for either party to assess the value of each individual component. Since Microsoft has created this difficulty for itself, it must bear the legal risks attendant to its way of business"); *Western Electric Co. v. Stewart-Warner Corp.*, 631 F.2d 333, 339 (4th Cir. 1980) (applying royalty to entire multi-component product because "it is much easier to ascertain the selling price of the finished product than the fair market value of one of its components").

Cytyc itself contends that it is difficult, if not impossible, to break out the value of the filter cylinder because it is not sold separately (even though it is). Prof. Cockburn opines that the parts have no value separately--they only have value when combined in a kit. **Hearing Vol. 3** at 111, *ll.* 17-18; *see also* p. 157 at *ll.* 1-4. Thus, the royalty must apply to the entire test kit.

d. The Entire Market Value Rule Prevents Cytyc from Manipulating Royalties

There is another reason for applying the rule. As Messrs. Duffy and Grinnell recalled, Cytyc threatened to "manipulate" the sales data to artificially lower DEKA's royalties. **Hearing Vol. 2** at 90-91 and 159-160; **Exh. 102**, Grinnell's Meeting Notes. But if the Entire Market Value Rule is applied, it will not matter how Cytyc manipulates ThinPrep prices. If Cytyc decides, for example, to give the filter cylinders away for free and charge $7 for the vials of solution, then DEKA will still earn a royalty. As Mr. Barry testified:

> Q. So let's assume that Cytyc always gave away the processors to sell all the disposables. Does that mean that DEKA should get no royalty on the processors?
>
> A. No.
>
> Q. Why not?
>
> CHAIRMAN MILONAS: Because it's common sense.

Hearing Vol. 2 at 251, ll. 13-20.

It's common sense that Cytyc could not sell disposables to labs that have no processors. Nor could Cytyc sell vials, slides, or collection devices but for the filter cylinders because the ThinPrep system does not work without them. Accordingly, the Entire Market Value Rule prevents Cytyc from shifting prices to deprive DEKA of its royalty.

Indeed, in the words of the *Western Electric* court, *supra*, it is "simply more convenient" to apply the 1% royalty to all sales of all disposables. *See* 631 F.2d at 339. This Entire Market Value method has the virtue that it is easy to apply and is consistent. This method also has the added benefit of reducing future disputes between DEKA and Cytyc and preventing Cytyc from adopting any other strategies that could reduce DEKA's royalties.

6. The Royalty Due on All Disposables Is Over $7.3 Million

Mr. Barry reviewed Cytyc's sales summaries and other accounting records to reconstruct the royalties as if the 1% rate had been applied to all sales of disposables. His calculations are reported in his expert report (**Exh. 130**) at pp. 7-8 and Exhibit 2. The shortfall was over $7.3 million through the June 2004, not counting interest. **Hearing Vol. 2** at 180; **Exh. 130**, Barry Report at 2, 7-8. Further calculations will be necessary to determine the shortfall of the last two quarters. But applying 1% to all sales of disposables will be an easy calculation for Cytyc.

B. CYTYC DOES NOT PAY 1% OF "NET SALES"

Even if the royalty is due only on filter cylinders, Cytyc's use of the cost ratio scheme to apportion sales of disposables does not satisfy the "Net Sales" requirement. First, the license agreement does not permit apportionment, let alone the use cost ratio to reduce Net Sales. Rather, the agreement requires that the royalty is paid on the sale price. Second, the relative cost of a component bundled with other items is not a proxy for its relative price. Third, cost ratio apportionment undervalues the filter and, as a result, Cytyc pays royalties that are far lower than if the filter cylinders were valued fairly and honestly. Cytyc has not paid a 1% royalty. It has paid no more than a 0.3% royalty.

1. The License Agreement Does Not Permit the Use of Cost

The agreement defines "Net Sales" to mean the "gross sales price" of a product less specified deductions (*e.g.*, freight, commissions, rebates). *Id.* at § 1(e). Net Sales includes any proceeds from the transfer of products to "unrelated customers" of Cytyc, whether through outright sales or through lease, rental, and licensing arrangements. *Id.* In other words, "Net Sales" means the market-driven price the customer pays, not the product's manufacturing cost.

On cross-examination, Mr. Sullivan finally admitted, in effect, that "Net Sales" is not determined by the cost to Cytyc. Rather, "Net Sales" means the market value of the product:

> Q. So the royalty is on net sales, which is determined in the marketplace, correct, the value of those sales?
>
> A. That's what the document says. It's "1 percent of the Net Sales of Products or Improvements."

Hearing Vol. 3 at 103, ll. 17-22 (emphasis added).

The agreement never mentions basing royalties on component costs, which are not determined in the marketplace. DEKA never told Cytyc that it could use cost to calculate royalties, either while negotiating the license agreement or afterwards. The record contains not even a suggestion that Cytyc ever mentioned the concept to DEKA until November 2001, when Cytyc sent the so-called "Singleton Letter" (**Exh. 15**). That letter marks the first time that DEKA ever heard of a cost ratio apportionment. **Hearing Vol. 2** at 104.

Cytyc's economics expert, Professor Cockburn, reviewed the license agreement and the correspondence evidencing its negotiation. He admitted that there was no "specific reference to a cost ratio" in either the agreement or in the negotiations. **Hearing Vol. 3** at 139, *ll.* 1-16. Likewise, Cytyc's former CFO, Bowen, testified that he reviewed the license agreement and could not recall any mention of cost ratio. **Exh. B**, Bowen depo. at 15-16.

New Hampshire contract law provides that a court should "where possible, avoid construing a contract in a manner that leads to harsh and unreasonable results or places one party at the mercy of others." *Anderson v. Century Prod. Co.*, 943 F. Supp. 137, 152 (D.N.H. 1996). Any reading of "Net Sales" that permits Cytyc to use cost ratio in place of the actual sales price to calculate royalties is unreasonable and places DEKA at Cytyc's mercy.

An interpretation that permits the use of cost would certainly be unreasonable. Prof. Cockburn admits that a rational actor would not have entered into a contract in which the royalty depended on the production cost of the royalty-bearing product. **Hearing Vol.** *3* at 161, *ll.* 23-24 ("Well, I think a rational actor would have entered into a different contract").

Moreover, Dean Kamen's assigned goal was to reduce component costs and, as such, he never would have agreed to a contract in which his royalty went down if the cost to make the component went down relative to other components. **Hearing Vol. 1** at 109-110; 196, *ll.* 5-12; 199, *ll.* 4-15. Kamen certainly did not expect to be penalized (by getting a lower royalty) simply because he helped Cytyc lower its manufacturing costs by designing cheaper disposables. *Id.*

But DEKA does get penalized because it cannot control Cytyc's costs. Consider the hypothetical in which Cytyc moves production of the filter cylinders to China and thus cuts the cost in half, to 10¢ from the alleged 21¢ per filter. Under that scenario, as Prof. Cockburn agreed, Cytyc makes a higher profit but cuts DEKA's royalty in half. *See* **Hearing Vol. 3** at 159-161. This cost fluctuation has actually happened. In 1999, the cost of the filter cylinders was higher and the resulting cost ratio was 39%. Thus, as DEKA later learned, Cytyc paid a 0.39% royalty. *See, e.g.*, **Exh. 158**, Royalty Schedule (Q3 1999); **Exh. 13**, "Historical Costs" spreadsheet. But Cytyc has since claimed to have reduced filter cylinder costs and thus has reduced its cost ratio to 29%. Cytyc now pays a royalty rate that is one quarter less, simply because the cost went down.[8]

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[8] Likewise, Cytyc could, in Bowen's words, "manipulate" royalties by arbitrarily subtracting 10¢ from the cost of the filters and adding 3.33¢ to each of the other three components. The resulting 10¢ swing would not change the overall 70¢ cost of the 4-part kit, and thus would not change Cytyc's $6.30 gross margin on a $7.00 kit. But it would halve DEKA's royalties by tilting the cost ratio. Even assuming Cytyc's cost shift was purely unrelated to royalties, DEKA would have no way to verify the costs because, as Mr. Duffy said, Cytyc will not share its confidential standard cost calculations. **Hearing Vol. 2** at 56-57.

Commentators on intellectual property licensing note that license partners seldom use cost as the basis for computing royalties:

> Licensing parties seldom agree to use cost or profits as a royalty base, because the licensee normally does not desire to divulge to the licensor any more proprietary business information than is necessary. Cost or profit bases also complicate the accounting process, since cost and profit figures are based on a variety of documents and accounting principles.

Finnegan & Mintz, "Determination of a Reasonable Royalty in Negotiating a License Agreement: Practical Pricing for Successful Technology Transfer," in *Licensing Law and Business Report* at p. 14 (1978) (included with DEKA's pre-hearing brief as Exh. T).

The problem of using cost cited by these commentators occurs here. DEKA cannot control how Cytyc calculates the standard costs it uses for its cost ratio apportionment. As Mr. Duffy, an experienced accountant, testified, the computation of standard cost is more art than science and can therefore vary from accountant to accountant. **Hearing Vol. 2** at 56. Indeed, as Judge Merhige observed, the standard cost could even include the vice president's salary (*Id.* at 28), which DEKA certainly cannot control. As shown above, even a small change in the claimed standard cost can dramatically reduce royalties. Moreover, Cytyc will not share with DEKA the details behind its standard cost calculations. **Hearing Vol. 2** at 56-57 and at 70. *ll.* 22-23. Cytyc regards that detail as highly confidential. **Exh. D**, Levitz depo. at 2210, *ll.* 14-22. Thus, DEKA has no way to verify Cytyc's costs and thus verify the royalty calculations.

2. Cytyc Admits that Relative Cost Is Not a Proxy for Relative Price

Price is a product of value, what the customer is willing to pay. Component cost, however, typically has little relationship to price, particularly in high-margin medical devices like the ThinPrep system. *See* **Exh. 127**, Goldscheider Rebuttal Report at ¶ 7; **Hearing Vol. 2** at 39, *ll.* 5-10. For example, Cytyc claims that the manufacturing cost of the filter cylinder in

recent years is about 21¢, while the cost of the entire 4-part kit is about 70¢. Yet Cytyc sells that 70¢ kit for $7.00-8.00, on average. *See, e.g.*, **Hearing Vol. 2** at 38, *ll.* 10-19. Thus, the mark-up on the kit is nearly 1000%. Something other than cost must drive this extraordinary mark-up.

Cytyc's CEO, Mr. Sullivan, testified that, in fact, the price of the ThinPrep products is not based on cost. Rather, as one would expect, it is based on market factors like competition, reimbursement, and what the market will bear. **Hearing Vol. 3** at 88, *ll.* 2-14; 99 at *ll.* 3-10.

Cytyc's former CFO, Mr. Bowen, testified that "[v]alue is a function of what the market will pay." To Bowen, the value of a product lies not in its cost, but rather in "what you sell it for." **Exh. B**, Bowen depo. at 64-67. Likewise, Cytyc's Rule 30(b)(6) designee, Mike Levitz, testified that "competitive factors" and "what the market will bear" help determine the price of the disposables, not cost. **Exh. D**, Levitz depo. at 160, *ll.* 14-16 and 161, *ll.* 6-12.

DEKA's accounting expert, Mr. Barry, opined that cost is not a proxy for the price of a component. **Hearing Vol.** 2 at 182-183. So did Mr. Duffy. *Id.* at 39, *ll.* 5-18 (There's no relation between cost and selling price in this case . . ."). And the Big-4 accounting firm that conducted the royalty audit, KPMG, reports that "the use of standard costs to apportion royalties is unusual and uncommon." **Exh. 114,** Audit Report of September 9, 2003, at p. 8, fn. 9.

3. Cost Ratio Apportionment Undervalues the Filter Cylinders

Cytyc's expert, Prof. Cockburn, agrees that, if sales revenue must be apportioned to isolate the revenue attributable to the filter cylinder, that apportionment should be based on the price--that is, how the customers value the product. He said, "Ideally, I think, in a perfect world, we'd be able to allocate these revenues on the basis of prices which reflect the value to the users of the individual components." **Hearing Vol. 3** at 111, *ll.* 5-8 (emphasis added).

Prof. Cockburn then opined, in effect, that this is not a perfect world because one cannot observe the prices--*i.e.*, the market value--of the individual components. He is wrong. Cytyc's sales and accounting records fully reveal the individual prices of the filter cylinder and other disposables. Thus, use of the cost ratio is not just wrong, it is unnecessary.

But Prof. Cockburn could not find the price in the accounting records because he is not an accountant. And, as he said, to associate the sales value with the products, you would have to ask an accountant. **Hearing Vol.** 3 at 127, *ll.* 2-8. Mr. Barry and Mr. Duffy are accountants, however. *Id.* at 9-12. So DEKA asked them to determine the true value of the disposables.

Messrs. Duffy and Barry reviewed Cytyc's accounting records and found that cost ratio apportionment does not accurately reflect the true sales value of the filter cylinder and hence its "Net Sales" price. Rather, cost ratio apportionment understates the value of the filter cylinders and thus artificially reduces DEKA's royalties. Cytyc multiples the cost ratio by the 1% royalty rate and pays a new royalty rate, of its own creation, of about 0.3%. Accordingly, Cytyc has breached the agreement because it has neither paid a full 1% nor based royalties on "Net Sales."

More specifically, Duffy and Barry looked at Cytyc's accounting and sales data and found that Cytyc does sell and price the filter cylinders separately. *See, e.g.*, **Hearing Vol. 2** at 105, *ll.* 1-9. Although Cytyc at first denied that it sells the filters separately, it now admits that it does. Mr. Bowen and other Cytyc employees admitted to DEKA's Duffy and Grinnell that Cytyc does sell the filters separately. **Hearing Vol. 2** at 158, *ll.* 2-8 and 160, *ll.* 12-22; **Exh. 101**, Grinnell's 5/2/02 Meeting Notes; **Exh. 102**, Grinnell's 5/21/02 Meeting Notes.

A good place to see these "stand-alone" sales of disposables is in Cytyc's sales summaries, such as **Exhs. 8** and **9**. (Exh. 8 shows the Fourth Quarter of 2002, while Exh. 9 shows the first three quarters of 2002.) A line item in these summaries, labeled "TransCyt Filter

Kit," represents sales of just the filter cylinders. **Exh. C**, Gilgun depo. at 54, *ll.* 2-18. Likewise, other line items in these summaries show separate sales of the vials ("PreservCyt Kit"), the collection devices (labeled "Papette" and "Assembly Kit"), and slides ("ThinPrep Slide Kit"). [9]

Mr. Barry tallied these line items from all of the Cytyc sales summaries and discovered that, from 1997 to 2002, Cytyc had sold about $ worth of filter cylinders in stand-alone domestic sales, *i.e.*, not as part of a test kit. Overall, including international sales, Mr. Barry tallied over in stand-alone sales. **Hearing Vol. 2** at 200, *ll.* 19-24 and at 243, *ll.* 14-23. To Mr. Barry, these numbers indicate the regular, ordinary course of business sales sufficient under GAAP to determine the price of filter cylinders. *Id.*

Based on these stand-alone sales of filters and other corroborating data gleaned from Cytyc's accounting records, Mr. Barry was able to determine the fair value of the various disposables and compare those fair values with the values determined under Cytyc's cost ratio apportionment. In each case, cost ratio apportionment understates the value of the filter cylinders and overstates the value of the vials, slides, and collection devices. For example:

* Filter cylinders sold separately in 2001 had an average price of , according to the sales summaries. But Cytyc's cost ratio apportionment yielded an average price in 2001 of only per filter cylinder when sold in the 4-part test kit. The

Confidential Financial Information Redacted

[9] Cytyc now admits that it does, in fact, sell the filter cylinders separately. *See* **Exh. C**, Gilgun depo. at 54, *ll.* 2-18; **Exh. D**, Levitz depo. at 178-179. Furthermore, as seen in the royalty reports, such as **Exh. 302** (at D 04267), Cytyc bases a royalty on 100% of the actual sales price of the filters when sold in the "TransCyt Filter Kit." Cytyc does not apportion those sales, as it does when the filter is sold in a 4-part kit. In other words, Cytyc itself treats the TransCyt Filter Kit as stand-alone filter sales, not as a 4-part kit. Accordingly, the Panel should reject Prof. Cockburn's litigation-inspired testimony that the "TransCyt Filter Kit" line item in the sales summaries really represents a 4-part kit and is just a keypunch error. He is not an accountant and has no first hand (or other) knowledge that any errors were made.

same disparity is seen in other years as well. *See* **Hearing Vol. 2** at 202-204; **Exh. 128,** Barry Rebuttal Report at 5 (in the table) and attached Exhibit 2.

* Cytyc's price lists show that Cytyc offers the ThinPrep Microscope Slide, Item # 70303-001, for $ /box of 500, or ¢ apiece. Likewise, the collection devices, Item # 70101-001 and # 70124-001, are listed at per package of 500, or apiece. *See* **Exh. 120**, Cytyc's 2004 Price List. Yet Cytyc's cost ratio yields values of about for the slides and for the collection devices. Thus, cost ratio apportionment overstates the value of the other disposables. **Hearing Vol. 2** at 206-20; **Exh. 128**, Barry Rebuttal Report at 5. By overstating the value of the other disposables, Cytyc shifts the value away from the filter.

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* Anyone can buy broom-like collection devices for 35¢ apiece from the manufacturer. Yet Cytyc's cost ratio apportionment, when applied to the average $ price of a 4-part kit, yields a value of about for the collection device. **Hearing Vol. 2** at 74, *ll.* 14-20 and 116, *ll.* 16-24; **Exh. 130**, Barry Report at 10.

* Cytyc's "Bill & Hold" documents (**Exh. 26**) show that it priced the vials of PreservCyt solution at apiece. In contrast, cost ratio apportionment yields the overstated value of about $: **Exh. 128**, Barry Rebuttal Report at 5. The manufacturing cost is about see **Exh. 13**, so the Bill & Hold price is not the vial's cost. Indeed, under GAAP and Cytyc's own revenue recognition policy (**Exh. 25**), Cytyc had to determine the sales price of the vials in those instances when it billed a customer for the complete test kit but did not immediately ship

the vials. In effect, Cytyc had to back out the price of the vials from the price of the entire kit and "unrecognize" that portion of the sales price on its books until the vials were shipped. Cytyc used a fair value method to determine the portion of the test kit price attributable to the vials. *See* **Hearing Vol. 2** at 76-80 and at 204-205; **Exh. 130**, Barry Expert Report at 9-10. Mr. Bowen, confirmed that Cytyc used the fair value, not cost ratio, for this calculation. **Exh. B**, Bowen depo. at 72-74 and 81-82.

Thus, when forced by Generally Accepted Accounting Principles ("GAAP") to determine the value of an individual component in the Bill & Hold analysis, Cytyc was able to do so. But when calculating DEKA's royalty, Cytyc ignored GAAP and claimed it was impossible to determine the value of the filter cylinders. Instead, Cytyc contrived a method based on manufacturing cost, not market value, to determine royalties. That was improper.

In any event, even assuming that this Panel determines that Cytyc properly excluded the other three disposables, Cytyc was still wrong not to use the fair value of the filter cylinders to determine royalties. Mr. Barry determined that, had Cytyc calculated royalties based on the fair value of the filter cylinders, rather than on the manufacturing cost ratio, Cytyc would have paid over $5.5 million more in royalties through the Second Quarter of 2004. **Exh. 130**, Barry Expert Report at 8-10. But as detailed below, even this fair value inquiry demonstrates that the only true way to compensate DEKA is to base the royalties on the entire set of disposables.

4. The Filter Cylinder Contributes the Most Value to the Test Kit

Mr. Barry testified that GAAP instructs accountants to use fair value (*i.e.*, arm's-length, market-driven selling price), not manufacturing cost, when necessary to "unbundle" the price of a component from the price of a larger package. **Hearing Vol. 2** at 182-184, 194-195; **Exh. 130**,

Barry Expert Report at 8-9; **Exh. 128**, Barry Rebuttal Report at 5-6. Mr. Barry did just that. As he testified, and as his calculations show, the filter cylinder generally contributed 82-86% of the sales price of the 4-part ThinPrep Pap Test kits in 1996-2002, depending on the year. *See* **Hearing Vol. 2** at 186-187; **Exh. 130**, Barry Expert Report at 8-10 and attached Exhibit 5. That percentage is a far cry from the 30% yielded by Cytyc's cost ratio apportionment. [10]

One might ask why the filter cylinder contributes so much of the value of a test kit. Market dynamics play a role. Mr. Barry concluded from Cytyc's accounting records that "[a]pparently the marketplace places a higher value on it relative to its cost of manufacture." **Hearing Vol. 2** at 232, *ll.* 2-13.

Indeed, Cytyc itself admits that the filter cylinder is the most important component to the operation of the ThinPrep system. In its own marketing brochure, Cytyc claims that the ThinPrep test works better than the rival SurePath test because of the filter cylinder and its interaction with FMS technology. Cytyc touts the "gentle vacuum . . . created within the filter," the "rate of flow through the filter" and the "rotating filter" as making the ThinPrep test more effective than the rival product, which does not use a filter cylinder or FMS. *See* **Exh. 121**, "The Test You Trust" brochure at 30586 (emphasis added). Nowhere does this product comparison mention any of the attributes of the preservative solution or other components.

Given that the filter cylinders contribute so much of the value of the 4-part test kits (*i.e.*, up to 86% of the value), applying the full 1% royalty to the entire "Net Sales" price of the kit (all four disposables) makes even more sense. Clearly, the filter cylinder is driving the market value

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[10] Even Prof. Cockburn admitted that GAAP is the "Bible" of accounting. **Hearing Vol. 3** at 124, *ll.* 7-11. Moreover, Cytyc relies on GAAP and uses it in its daily accounting activities. **Exh. B**, Bowen depo. at 75, *ll.* 19-21. As Mr. Barry explained, GAAP requires that price, not cost, be used for allocating royalties on bundled components.

of the test kit and thus, under even the most stringent interpretation of the Entire Market Value Rule, the royalty should apply to the entire functional unit.

C. CYTYC'S OTHER BREACHES

Cytyc changed its royalty calculation methods at least three times since 1996. *See, e.g.*, **Exh. D**, Levitz depo. at 59-60, 65, 74, and 216. In 1996-97, it used a 20% allocation to apportion sales of disposables. *Id.* at 60. In other words, instead of paying a 1% royalty, Cytyc paid a 0.2% royalty. To this day, Cytyc cannot explain how that 0.2% royalty was derived. **Exh. F,** Cockburn depo. at 102 (statement by Cytyc's counsel). DEKA did not learn of this method until it was revealed in the KPMG audit report in 2003. **Hearing Vol. 2** at 98-99. The license agreement requires 1%, not a 0.2% royalty. Accordingly, Cytyc underpaid royalties in 1996-97.

The next change was the adoption of cost ratio apportionment in 1998, which Cytyc never disclosed to DEKA until it sent the "Singleton Letter" (**Exh. 15**) in November 2001. The third change, as reported in the Singleton Letter, was the retroactive coupling of Laboratory Kits and Physician Kits. Cytyc breached the agreement by retroactively treating these separate products as two halves of a whole and thereby diluting the royalties. Specifically, Cytyc used to treat Lab Kits and Physician Kits as separate products when applying its improper cost ratio apportionment. That is, Cytyc compared the manufacturing cost of the filter cylinder with the total cost of the Lab Kit, which includes only filter cylinders and slides. That cost ratio of filter to Lab Kit was 70-80%, as seen in the "Laboratory Supplies" line of the royalty reports. *See, e.g.*, **Exh. 293** and **295** (royalty reports from 1999 and 2000). When Cytyc retroactively recalculated royalties in November 2001, however, it treated the Lab Kits and Physician Kits as one fictional 4-part kit and thus diluted the cost ratio of the filter to 30% (because the filter cost was now

being compared with the cost of all four disposables, not just two). As a result, Cytyc claimed that it had overpaid DEKA by over $426,639 and wrongfully reclaimed that amount. **Exh. 15.**

As both Duffy and Barry found, however, Cytyc sells the kits as two separate products and does not market them as an integral 4-part kit. **Hearing Vol. 2** at 64-66; **Exh. 130**, Barry Report at 6. For example, Cytyc's sales summaries show substantial revenue recorded for Physician Kits, even though Cytyc had told Mr. Duffy that, because it treated the Lab and Physician Kits as one integral kit, it placed all of the revenue on the Lab Kits and charged nothing for the Physician Kits. **Hearing Vol. 2** at 57, *ll.* 6-24. Cytyc sells the kits separately and thus records the revenue separately. Indeed, the two kits are offered as separately-priced products in Cytyc's customer price lists. *See* **Exhs. 11, 12,** and **120.**

Moreover, as Mr. Barry discovered, Cytyc's sales summaries show that Cytyc has actually sold three times as many Lab Kits as Physician Kits. **Exh. 130**, Barry Expert Report at 6; *see also* **Hearing Vol. 2** at 65, ll. 17-19. Indeed, as Cytyc's Mr. Gilgun admitted, the ratio of Lab to Physician Kits was 5-to-1 in 2002 alone. *See* **Exh. C**, Gilgun depo. at 96, *ll.* 15-22; 98-99; and 101-104. These statistics shows that the two kits are separate products and are not sold as one 4-part kit. If they were, one would expect to see closer to a 1-to-1 sales ratio.

Cytyc's own documents, therefore, belie Cytyc's arguments. Cytyc should pay back the royalties it retroactively withheld from DEKA.

D. CYTYC OWES THE COST OF THE AUDIT

Section 3.03 of the license agreement grants DEKA the right to audit Cytyc's royalty payments at its own expense, except when "there has been an underpayment of Cytyc's royalty obligations hereunder in excess of $10,000 for the period which is subject to the audit." In that case, "Cytyc shall reimburse DEKA for the cost of such audit."

For the audited period (1996-2002), the underpayment was well over the contractual $10,000, and Cytyc thus owes DEKA the audit costs. Specifically, in 2002, DEKA engaged the Big-4 accounting firm KPMG to audit Cytyc. The audit covered "the period beginning January 1, 1996 and ending September 30, 2002." **Exh. 114**, KPMG Audit Report at 3. KPMG found that, even under Cytyc's disputed cost ratio and 20% methods, Cytyc had still failed to account for all ThinPrep sales and had thus underpaid royalties by at least $31,084 in 1996-1997 and $5,678 in 1998, for a total underpayment of $36,762 in just those three years alone. **Exh. 114** at 10. KPMG further found that, if Cytyc had paid a full 1% on all disposables, as it should have, then the royalty underpayment was actually $4,100,503 for the audited period. *Id.* at 12.

Mr. Barry audited the same period (and also up to June 2004) using Cytyc accounting records not made available to KPMG. Barry found shortfalls of as much as $7.3 million. Barry also confirmed KPMG's calculation of the 1996-97 shortfall under Cytyc's own improper cost ratio method. **Exh. 130**, Barry Expert Report at 2.

Mr. Duffy testified that DEKA paid KPMG over $150,000 for conducting the audit. **Hearing Vol. 2** at 97, *ll.* 14-15. In fact, KPMG's invoices total $155,758. *See* **Exh. 132**, KPMG invoices. Thus, Cytyc owes DEKA $155,758 in addition to the royalty underpayments.

III. CYTYC BREACHED ITS DUTIES OF TRUST AND FAIR DEALING

Cytyc owed DEKA a fiduciary duty to calculate and report royalties fairly and accurately. Such a duty arises when an inventor entrusts another to commercially exploit his or her ideas. *See, e.g., City of Hope Nat'l Med. Center v. Genentech*, 20 Cal. Rptr.3d 234, 264 (Cal. Ct. App. 2004); *Crutcher-Rolfs-Cummings, Inc. v. Ballard*, 540 S.W.2d 380, 387 (Tex. Civ. App. 1976) (confidential relationship was formed when inventor entrusted his ideas to manufacturer). The

inventor is thus entitled to trust the licensees' royalty calculations. *City of Hope,* 20 Cal. Rptr.3d at 268 (licensee had duty of "keeping and furnishing honest accountings").[11]

As detailed in Section I, DEKA contributed confidential "know-how" to Cytyc. Cytyc was bound to keep DEKA's know-how confidential. *See* **Exh. 40**, License Agreement at § 7.01. Moreover, Cytyc was bound to "use all reasonable efforts . . . to maximize the sales of Products or Improvements." *Id.* at § 6.01 (emphasis added). That is, DEKA gave its know-how in exchange for Cytyc's promise that it would maximize sales and thus maximize royalties.

DEKA and Cytyc were, in effect, partners. DEKA subsidized the development of the ThinPrep prototypes and billed Cytyc only 50% of the costs. DEKA made many concessions to Cytyc so that the young company could survive and gain venture financing. DEKA lent Cytyc its good name so that Cytyc could raise $5 million from investors. DEKA developed and built the ThinPrep prototypes so that Cytyc could focus on developing the Imager. DEKA even received an equity stake. (A shareholder is absolutely owed a fiduciary duty.) DEKA solved Cytyc's problem and gave it the solution to building a slide preparation system.

Cytyc was thankful for DEKA's contributions and concessions and was thus content to pay royalties based on a "handshake understanding." **Exh. 176** at p. 20406. That statement shows that Kamen and Lapidus had more than a typical arms-length business relationship. It shows that the parties trusted each other. Clearly Cytyc owes DEKA a duty of trust for all that DEKA contributed.

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[11] New Hampshire would likely follow *City of Hope* and impose upon Cytyc a fiduciary duty here. New Hampshire recognizes a liberalizing trend in imposing fiduciary duties to prevent unjust enrichment. *Lash v. Cheshire County Sav. Bank, Inc.*, 474 A.2d 980, 981 (1984).

A fiduciary must act with the utmost good faith and fairness. *Lash*, 474 A.2d at 981. Likewise, New Hampshire law imposes a duty of good faith and fair dealing in the performance of a contract and limits a party's discretion in meeting its obligations. *Centronics Corp. v. Genicom Corp.*, 562 A.2d 187, 190 (N.H. 1989). This duty requires a party to make every effort to increase the value of performance to the other party. *Id.* at 143.[12]

In this case, Cytyc breached its duties of trust and good faith in several ways. First, Cytyc kept changing the way it calculates royalties, each time choosing a method that reduced DEKA's already modest royalty through arbitrary and unilateral means. Cytyc never called or wrote DEKA to ask permission to change the calculation methods. **Hearing Vol. 2** at 104, *ll.* 8-20. Nor did Cytyc ever explain its calculation methods to DEKA and only revealed cost ratio apportionment for the first time in the Singleton Letter (**Exh. 15**). Second, in November 2001, Cytyc decided, without input from DEKA, to withhold over $400,000 in royalties on the flimsy premise that two separate products--the Lab and Physician Kits--should be treated as a fictional 4-part test kit. *See* **Exh. 15**, Singleton Letter. Third, when DEKA attempted to investigate the royalty shortfall, Cytyc (specifically its CFO, Bowen) threatened that it would "manipulate" the financial data to keep DEKA's royalties down. **Hearing Vol. 2** at 90-91 and 160; **Exh. 102,** Grinnell's Meeting Notes. Fourth, Cytyc forced DEKA to seek an expensive audit to uncover Cytyc's concealed royalty calculations and then hampered the progress of the audit. Indeed, Brendan Duffy visited Cytyc three times in hopes of getting the accounting data he needed to

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[12] A breach of trust or duty of good faith also constitutes a violation of New Hampshire's unfair or deceptive trade practices act, RSA 358-A. *Milford Lumber Co. v. RCB Realty, Inc.*, 780 A.2d 1259, 1263 (N.H. 2001). Cytyc's unfair and deceptive conduct entitles DEKA to its attorneys' fees and costs. Moreover, Mr. Goldscheider opines that Cytyc's conduct was willful. **Hearing Vol. 2** at 294, *ll.* 12-21; **Exh. 126**, Goldscheider Report at ¶¶ 60-61. Under RSA 358-A:10, this Panel can award treble damages for such willfulness.

piece together Cytyc's deceptive accounting and thus avoid the audit. **Hearing Vol. 2** at 88-89. Duffy even warned Cytyc that an audit would be costly for both parties. *Id.* at 89. *ll.* 8-21. But Cytyc told him that it would not cooperate any further and that DEKA would have to incur the expense of an audit. *See* **Exh. 260**, Letter from Mike Gilgun to Brendan Duffy dated May 15, 2002. All of this conduct is unfair. Cytyc did not account for the royalties fairly or openly.

IV. DEKA DILIGENTLY PURSUED ITS RIGHTS

Cytyc has argued that DEKA's claims are barred or limited on statute of limitations, laches, and waiver grounds. But Cytyc deceived DEKA, hiding its underpayments in complex royalty calculation methods that even Cytyc itself can barely explain. Accordingly, DEKA's claims are not barred or limited because DEKA did not discover--nor could have discovered--the underpayments until November 2001 at the earliest, when Cytyc's Meridith Singleton sent the now infamous letter (**Exh. 15**) seeking to reclaim over $400,000 in royalties. Moreover, Cytyc's breach of its fiduciary duty and its unfair and deceptive accounting excuse any alleged delay in filing suit. Cytyc cannot be allowed to profit from its own wrongful acts.

A. DEKA COULD NOT HAVE DISCOVERED CYTYC'S BREACHES

In New Hampshire, the limitations period does not begin to run until "the plaintiff discovers, or in the exercise of reasonable diligence should have discovered, the injury and its causal relationship to the act or omission complained of." RSA 508:4. This "discovery rule" applies to all personal causes of action, including breach of contract, breach of good faith and fair dealing, breach of trust, and unfair trade practice claims. *See Black Bear Lodge v. Trillium Corp.*, 620 A.2d 428, 429-30 (N.H. 1993). Likewise, "laches cannot be imputed to a party who is ignorant of the facts creating his right." *Healey v. Town of New Durham Zoning Bd. Of Adjustment*, 665 A.2d 360, 368 (N.H. 1995).

The first time DEKA had any reason to believe there was a problem with Cytyc's royalty payments was November 27, 2001, when DEKA received the Singleton Letter (**Exh. 15**). And even then, the Singleton Letter was confusing to both Kamen and Duffy. **Hearing Vol. 1** at 143, *ll.* 2-10 and 145 at *ll.* 8-15; **Hearing Vol. 2** at 22-24. Mr. Kamen testified that this letter triggered DEKA's inquiry into Cytyc's royalty calculations. **Hearing Vol. 1** at 144-145. DEKA filed this arbitration on November 17, 2003, just under two years later.

In particular, Cytyc's royalty reports gave DEKA no reason to question the calculations. Through 1997, the reports provided little or no detail. The 1996-97 reports were just a check itself, with no detail shown. *See, e.g.*, **Exhs. 286-290** (1996-97 royalty reports received by DEKA). So DEKA certainly would have no way of knowing that in 1996-97, Cytyc was using the 20% allocation method to reduce the royalty rate to 0.2% or that Cytyc was paying royalties only on filter cylinders. It did not occur, and would not have occurred, to Kamen that Cytyc would go out of its way to reduce the already low 1% royalty. **Hearing Vol. 1** at 146, *ll.* 17-22.

In 1998, Cytyc started sending a one-page summary of the royalty totals. *See, e.g.*, **Exhs. 291-300** (royalty reports sent to DEKA from 1998-May 2001). But these one-page summaries hardly shed light on Cytyc's calculations. Mr. Kamen did not know what a "ThinPrep Pap Test" was. He assumed that the term "Test" referred to revenues from the performance of a test--*i.e.*, the lab service of using the Imager to read a slide to look for malignancies. Kamen thought that the 30% of the test revenue allocated to royalties was the revenue from all disposables in a kit used as part of the "test." **Hearing Vol. 1** at 147-49 Certainly nothing on these summaries told Kamen or DEKA that the royalties were being limited only to the filter cylinders. Nor did anything on these summaries say that Cytyc was using its cost ratio scheme--which DEKA never even dreamed about--to reduce the royalties. *Id.*; **Hearing Vol. 2** at 11-12.

Also, as Mr. Duffy testified, Cytyc never notified DEKA of its changes in methodology in 1996 and again in 1998. *See* **Hearing Vol. 2.** at 104, *ll.* 8-20 ("The only correspondence was when [Cytyc] made the third change [in 2001] and they wanted money back.").

Even Cytyc's own CEO, Mr. Sullivan, could not identify the products included in the various line items on these royalty schedules. For example, he could not identify the "PreservCyt Kit," the "TransCyt Filter Kit" or the "TransCyt Blue Filter 100" line items. **Hearing Vol. 3** at 81-82. Nor could Prof. Cockburn identify the "Other Sales" line item. *Id.* at 147, *ll.* 1-20. Prof. Cockburn also testified that the royalty reports contained mischaracterizations (*Id.* at 144, *ll.* 16-18) and that Cytyc itself took four years to recognize its own alleged "mistake" in calculating royalties. *Id.* at 145-146. He agreed that "[s]ome mistakes are very difficult to discover." *Id.*

DEKA certainly could not decipher Cytyc's opaque royalty schedules nor begin to recognize that Cytyc used cost ratio apportionment. Indeed, the 1% royalty is so low, DEKA could not possibly have imagined that Cytyc would "go out of their way to reduce a 1 percent royalty." **Hearing Vol. 1** at 146, *ll.* 17-22. Even Cytyc itself cannot identify all the line items on the royalty reports. Because Cytyc, which controls the data, took four years to recognize its own "mistake," the Panel should reject Cytyc's laches, limitations, and waiver challenges.

B. CYTYC'S UNCLEAN HANDS EXCUSE DEKA'S ALLEGED DELAY

A finding of laches "depends upon the conduct and situation of all the parties, not solely upon those of one." *New Hampshire Donuts, Inc. v. Skipitaris*, 533 A.2d 351, 356 (N.H. 1987). Thus, when the party claiming laches or waiver has contributed to the alleged delay, that delay in bringing suit should be excused. *Id.* Moreover, given its fiduciary duty, Cytyc cannot be heard to argue that DEKA's claims are barred. DEKA was entitled to trust Cytyc's royalty statements and had no duty to verify the calculations. *See City of Hope*, 20 Cal. Rptr.3d at 263. Given that

Cytyc withheld its various royalty methods from DEKA, there can be no laches or waiver. *New Hampshire Donuts*, 533 A.2d at 356 (no laches when defendant hampers discovery of the harm).

Cytyc's refrain throughout this case, and a question that it has asked each DEKA witness at depositions, is something to the effect of, "If you were confused by the royalty report, couldn't you just pick up the phone and call Cytyc?" But as Mr. Duffy learned, calling Cytyc would have done no good. **Hearing Vol. 2** at 106-107. In particular, as Mr. Duffy learned, to his frustration, Cytyc refused to give DEKA the basic information it needed to verify the royalties. For example, even though Cytyc ultimately bases cost ratio apportionment on its standard costs, it has never given DEKA the details of its standard cost calculations. *Id.* at 70, *ll.* 22-23 ("To this day I still don't have the details on the standard costs"). Cytyc even forced DEKA to conduct an expensive audit instead of just giving Mr. Duffy the information he needed. *Id.* at 88-89.

Even the Singleton Letter, which triggered this matter, contains several misrepresentations, as Mr. Kamen testified. **Hearing Vol. 1** at 145, *ll.* 13-15. For example, the letter says that "Cytyc does not sell or price the filter separately." **Exh. 15**. But as Messrs. Duffy, Grinnell, and. Barry later learned, Cytyc regularly sells the filter cylinders separately. *See* **Hearing Vol. 2** at 105, *ll.* 1-14 and 160, *ll.* 12-22); **Exh. 102**, Grinnell Meeting Notes ("Bob states for first time that they sell each"); **Exh. 128,** Barry Rebuttal Report at 2.

So Cytyc misled DEKA, covered up its royalty calculations, and never once consulted with DEKA about how to calculate the royalties. Cytyc did not act fairly and instead tried to disguise its royalty reduction schemes. Indeed, Cytyc had good reason to hide its cost ratio scheme because, as Prof. Cockburn testified, no rational person would have agreed to it. Thus, DEKA should not be penalized for Cytyc's own misdeeds. Rather, given Cytyc's willfulness, DEKA should receive treble damages.

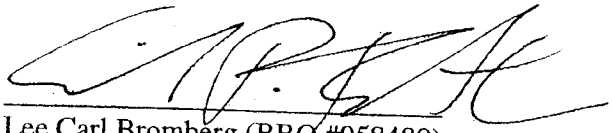
CONCLUSION

DEKA respectfully asks this Panel for an award of royalties in the amount of $7,366,008 (through June 2004), plus interest, and an order compelling Cytyc to pay the full 1% of "Net Sales" of total disposables for the full term of the license agreement. DEKA further requests that the Panel award attorneys' fees, costs, and treble damages for Cytyc's willful misconduct. Finally, DEKA requests that the Panel order Cytyc to reimburse the audit costs of $155, 758.

Dated: January 21, 2004

Respectfully submitted,

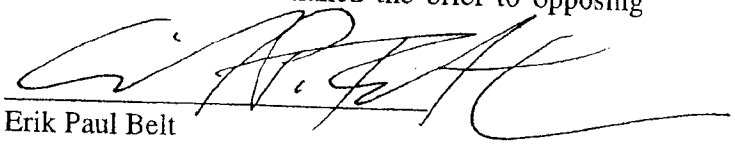
DEKA PRODUCTS LIMITED PARTNERSHIP
By its attorneys,



Lee Carl Bromberg (BBO #058480)
Erik Paul Belt (BBO #558620)
BROMBERG & SUNSTEIN, LLP
125 Summer Street, Suite 1100
Boston, MA 02110-1618
(617) 443-9292

CERTIFICATE OF SERVICE

I certify that, on the above date, I sent, by overnight delivery, true copies of this brief to each of the three arbitrators and to opposing counsel and also e-mailed the brief to opposing counsel.



Erik Paul Belt

01062/00507 359179.1

EXHIBIT 16

AMERICAN ARBITRATION ASSOCIATION

DEKA PRODUCTS LIMITED PARTNERSHIP, Claimant v. CYTYC CORPORATION, Respondent.	Case No. 11 Y 133 02624 03

DEKA'S REPLY TO
CYTYC'S POST-HEARING BRIEF

CONTAINS INFORMATION THAT HAS BEEN DESIGNATED AS CONFIDENTIAL UNDER THE PROTECTIVE ORDER

Lee Carl Bromberg
Erik Paul Belt
Bromberg & Sunstein LLP
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Attorneys for

DEKA PRODUCTS LIMITED PARTNERSHIP

January 28, 2004

Contrary to Cytyc's main argument, the license agreement expressly provides for a royalty on, in Dean Kamen's words, "whatever it takes to make a slide." But Cytyc ignores the actual wording of the contract and instead focuses on preliminary correspondence exchanged years before the agreement was finalized. In touting that parol evidence, Cytyc also ignores its own performance in which it originally paid royalties on "total" disposables.

Cytyc also withheld key documents that specifically contradict Cytyc's statements.[1] Cytyc's actions in withholding key documents and in glossing over crucial evidence epitomize its business dealings with DEKA over the past decade--using sharp tactics to obfuscate the facts and deprive DEKA of its bargained-for rights under the License Agreement.

I. THE ROYALTY APPLIES TO ALL DISPOSABLES

The agreement recites the intent to include all technology used for preparing slides:

> DEKA wishes to license to Cytyc the right to utilize FMS Technology to facilitate the preparation of slides . . . Cytyc is willing to limit the use of both FMS Technology and Cytyc Technology to the preparation of slides

Exh. 40, License Agreement at "Recitals" (emphasis added).

Moreover, DEKA developed not just a processor and filter cylinder, but also "a method and apparatus . . . for the preparation of slides." *Id.* (emphasis added). DEKA should be compensated for the technology it contributed, including the method. That method uses not just a filter cylinder, but also a vial of fluid (*i.e.*, preservative solution), slide, and collection device.[2]

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[1] This Panel ordered Cytyc to produce all of its FDA applications. Cytyc produced some FDA documents but withheld others. DEKA discovered this omission, confronted Cytyc, and Cytyc finally produced the documents on the second day of the hearing, too late to be useful.

[2] These disposables certainly utilize FMS and/or Cytyc Technology. For example, the method disclosed in the '084 Patent, which is part of both FMS and Cytyc Technology, requires a "specimen container 14" (e.g., a vial) "that contains the liquid 16 that carries the cells." **Exh. 39,** '084 Patent at 02143 (Col. 5, *ll.* 8-9). That method includes "the transfer of the collected cells from the filter 12 to the microscope slide." *Id.* at Col. 6, *ll.* 28-29 (emphasis added).

The definition of "Product Disposables" confirms that the parties intended that any disposable sold by Cytyc for practicing the ThinPrep method should be included in the royalty base. The definition states that "Product Disposables presently includes Cytyc's 'TransCyt Filters.'" **Exh. 40**, Agreement at § 1.01(g) (emphasis added). The word "presently" shows that the parties anticipated that Cytyc might supply additional disposables not yet finalized (or even envisioned)--i.*e.* "similar disposables"--and that they should be included in the royalty base.[3]

Yes, Kamen knew back in the early 1990s that one needed solution and slides to practice the ThinPrep method. But that does not mean that DEKA was told, or that Cytyc knew, what disposables Cytyc would supply beyond the filter cylinders. For example, the withheld FDA documents prove that in 1991-92, Cytyc did not yet plan to provide slides and collection devices. Instead, Cytyc told the FDA that "standard" slides and any existing collection device should be used, thus belying Cytyc's assertion that ThinPrep required proprietary slides or specific devices. *See* **Tab 1**, *Cytyc ThinPrep® Processor Original Premarket Application*, dated March 11, 1992, at 29-30 (under "Required Supplies," listing "Standard glass microscope slide (not provided)") (emphasis added); **Tab 2**, *ThinPrep Processor 510(k)*, dated April 22, 1991, at 4.

Thus, the parties included what they then "presently" understood Cytyc would be supplying and left room for not yet specified "similar disposables" and "Improvements," which are expressly part of the royalty base. Indeed, based on Lapidus's "handshake understanding,"

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[3] Cytyc relies on a canon of construction, "*expressio unius est exclusio alterius*," for the proposition that other disposables are excluded from the agreement. That canon, however, "is only a guide, whose fallibility can be shown by contrary indications." *United States v. Vonn*, 535 U.S. 55, 65 (2002). Here, the term "Product Disposables" contains such "contrary indications" because it includes not just a filter cylinder but also any "similar disposable," which broadly refers to any other disposable needed to make a slide. Moreover, "similar disposable" cannot mean merely an improved filter, as Cytyc contends, because the term "Improvements" already expressly covers that contingency. Conflating those two terms is legally improper.

Exh. 176 at 20406, Cytyc began paying royalties on "Disposables (Total)," *Id.* at 20407. The word "Total" emphasizes that the royalty was not based on only a portion of total disposable sales but instead on total disposables, period.

II. CYTYC IMPROPERLY ADOPTED ITS COST RATIO SCHEME

Cytyc never consulted DEKA before adopting its cost ratio scheme and has never explained its failure to do so.[4] Rather than trying to justify its actions, Cytyc contends that cost ratio is somehow authorized unless it can be deemed "irrational." This is not the law. A party must choose the approach that avoids "depriv[ing] another party of a substantial proportion of the agreement's value." *Centronics Corp. v. Genicom Corp.*, 562 A.2d 187, 193 (N.H. 1989).

DEKA never would have consented to cost ratio because (a) it bases royalties on manufacturing costs rather than on the required "Net Sales," (b) penalizes DEKA for achieving its assigned goal--designing low cost disposables; and (c) discards royalties on total disposables. Cytyc's use of cost ratio thus deprives DEKA of a substantial portion of the agreement's value. That breach of conduct entitles DEKA to multiple damages. *See Globe Distrib., Inc. v. Adolf Coors Co.*, 129 B.R. 304, 317, 321 (Bankr. D.N.H. 1991) (defendant breached duty of good faith by choosing contract option more detrimental to plaintiff, entitling it to double damages).

In any event, cost ratio apportionment is not rational because it undervalues the filter cylinders and overvalues the other three disposables, as Mr. Barry explained. Indeed, Mr. Barry found that Cytyc's own sales and accounting records value the filter at 82-86% of the value of

---

[4] Prof. Cockburn's admission that a rational actor would not accept cost ratio may explain Cytyc's failure to consult DEKA. Moreover, the only license agreement that Cytyc could offer that employs cost ratio is an agreement that Cytyc itself prepared and signed with U.Mass in July 2004--after this arbitration began. The Cytyc/U.Mass license expressly dictates the use of cost ratio. *See* **Exh. 122**, U.Mass License at 31935. In sharp contrast, the DEKA/Cytyc agreement contains no express mention of cost ratio. It was never considered.

the 4-part test kit. *See* **Hearing Vol. 2** at 186-87. Moreover, cost ratio is neither "observable" nor "reliable," as Cytyc argues. First, Cytyc has never provided DEKA with the details behind its costs. Thus, DEKA has no way to observe Cytyc's calculations. Second, as it admitted at the hearing, Cytyc has made many calculation errors while implementing its complicated scheme. Indeed, as even Cytyc admits, costs can fluctuate. Cytyc's Brief at 31. In 1999, Cytyc's claimed cost ratio was 39% and, by 2002, only 29%. That change has increased Cytyc's profits while further reducing DEKA's royalty rate by one-fourth. Cost ratio is neither rational nor reliable.[5]

III. DEKA HAD NO REASON TO QUESTION THE ROYALTIES

As seen above, Cytyc originally paid royalties on "Disposables (Total)." Thus, when DEKA signed the agreement in 1993, and for years thereafter, DEKA had reason to believe that it was receiving royalties on all disposables. And Mr. Kamen assumed that Cytyc was correctly tabulating royalties because "I trust my partners." **Exh. 387**, Kamen depo. at 75, *ll.* 13-16.

Starting in 1998, Cytyc began sending a one-page schedule with its royalty payments. *See, e.g.*, **Exh. 291**. While these schedules indicate in hindsight that not all of the revenue was subject to royalties, DEKA did not suspect, and could not have suspected, foul play then. DEKA believed that many of the line items, such as "ThinPrep Pap Test," included, *e.g.*, lab services not subject to royalties. Mr. Barry had a similar reaction. **Tab 3**, Barry depo. at 82, *ll.* 6-12. Even Cytyc's "Glossary of Terms" acknowledges this ambiguity. It defines "ThinPrep Pap Test" as "A Pap smear screen [*i.e.*, test] performed using a slide prepared by the ThinPrep system," not as the kit of disposables for preparing the slide. *See* Appendix A to Cytyc's Brief at v (emphasis added). Cytyc itself has thus caused this confusion.

---

[5] Moreover, cost ratio is subject to manipulation that the Entire Market Value Rule (EMVR) would prevent. Cytyc's CFO threatened to "manipulate" the data under Cytyc's control to artificially lower DEKA's royalties. Such conduct proves the wisdom of applying EMVR.

Cytyc cites Mr. Barry's deposition for the proposition that the royalty schedules fully disclosed Cytyc's cost ratio. *See* Cytyc's Brief at 15. But Cytyc overstates what Barry said. Cytyc asked for Barry's hindsight view as an accounting expert, and Mr. Barry answered "with hindsight." But when Cytyc asked Barry to put aside hindsight and instead put himself in the shoes of DEKA circa 1998, Barry testified that the schedules would not have been clear:

> Q. If you had been the CFO of DEKA in June 1998 and you had received this document [Exh. 291], would you have understood the basis for Cytyc's royalty payments?
>
> A. Not fully, no.

Tab 3, Barry depo. at 82, *ll.* 13-17. Indeed, Mr. Barry reviewed all of the royalty statements and testified that the Singleton Letter of November 27, 2001, "is the first time it was indicated that a cost--relative cost method was being used." **Tab 3**, Barry depo. at 93, *ll.* 9-16.[6]

IV. CYTYC'S UNDERPAYMENT ENTITLES DEKA TO ITS AUDIT COSTS

Cytyc strains the wording of the audit clause (§ 3.03) to require an underpayment of over $10,000 in one calendar year before Cytyc is liable for audit costs. As KPMG reported, however, Cytyc underpaid by more than $10,000 in 1997 alone, so the point is moot. Cytyc has deliberately confused the frequency of audits ("once in any calendar year") with "the period which is subject to the audit" to create its argument. The period subject to audit was 1996-2002. Thus, Cytyc owes DEKA $155,558 for its audit costs.

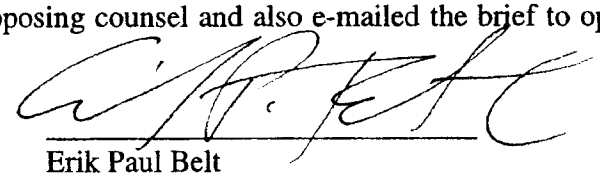
Dated: January 28, 2005

Erik Paul Belt
On behalf of
DEKA PRODUCTS LIMITED PARTNERSHIP

[6] Cytyc should not be allowed to cite Barry's deposition because Cytyc could have cross-examined him on the alleged clarity of the royalty statements at the hearing. Cytyc never did and has thus waived the point. DEKA includes Barry's deposition testimony to complete the record.

CERTIFICATE OF SERVICE

I certify that, on January 28, 2005, I sent, by overnight delivery, true copies of this brief to each of the three arbitrators and to opposing counsel and also e-mailed the brief to opposing counsel.



Erik Paul Belt

01062/00507 360445.1

EXHIBIT 17

CHECK NO.	TO THE ORDER OF	DATE	GROSS AMOUNT	DISCOUNT	CHECK AMOUNT
W1+	DEKA Products Limited Partnership	1/16/92	5795300		595300

DETACH AND RETAIN FOR YOUR RECORDS

CYTYC CORPORATION

CYTYC
corporation
237 CEDAR HILL STREET
MARLBOROUGH, MA 01752
TEL: (508) 481-1341

DATE	INVOICE	AMOUNT

5-39/110

1512

Jan. 16, 1992

PAY Five thousand nine hundred fifty three and XX/100 DOLLARS $5953.00

TO THE ORDER OF DEKA Products Limited Partnership

BANK OF BOSTON
THE FIRST NATIONAL BANK OF BOSTON

⑈001512⑈ ⑆011000390⑆511 559116⑈

EXHIBIT
tabbies
ARBITRATION
176

CYTYC 20405
CONFIDENTIAL

CYTYC
corporation

January 13, 1992

Mr. Dean Kamen
DEKA Products Limited Partnership
c/o DEKA Research and Development Company
340 Commercial Street
Manchester, NH 03101

Dear Dean,

I am sorry that Cytyc wasn't able to participate in your US First event. Don't, however, count us out for the future!

I'm enclosing a royalty check based on ThinPrep sales for 1991. The ThinPrep is off to a good start and I hope to send you larger checks in the future. I'm sending you this check even though we have not yet consummated the royalty agreement. I would prefer to pay you your royalty under a signed agreement, but am content doing it on the basis of our handshake understanding. Perhaps you could have a word with Steve Hazard.

Best regards for the new year.

Sincerely,

Stanley N. Lapidus
President

237 Cedar Hill Street · Marlborough, MA 01752 · Tel: (508) 481-1341 · Fax: (508) 481-2173

CYTYC CORP.

ROYALTY CALCULATION - 1991

	Initials	Date
Prepared By	EGO	
Approved By		

WILSON JONES COMPANY G7504 ColumnWrite MADE IN U.S.A.

		1	2	3	4
			Quantity	$ Sales	
1	Adjusted Sales - Thin Prep		33	5297775	
2					
3	Disposables (Total)		85	6552000	
4					
5	Total Sales - 1991			59529975	
6					
7	Total Sales - 1991			59529975	
8	1% Royalty			1%	
9	1991 Accrued Royalty			595300	
10					
11					
12					
13					
14					
15					
16	Accrued Royalties 2350				
17	Balance 11/30/91	830945			
18	Less: JE 1291 to adjust				
19	Deferred Income - Service				
20	amounts incorrectly entered	(300000)			
21	Add: December royalty expense	64355			
22	Adjusted 1991 total	595300			
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
36					
37					
38					
39					
40					

EXHIBIT 18

PEPE & HAZARD

LAW OFFICES

GOODWIN SQUARE
HARTFORD, CONNECTICUT 06103-4302
203/522-5175 FACSIMILE 203/522-2796

October 14, 1991

VIA FAX

Mr. Stanley N. Lapidus
Cytyc Corporation
237 Cedar Hill Street
Marlborough, MA 01752

EXHIBIT
Stricker
ARBITRATION
86

Re: License Agreement w/DEKA

Dear Mr. Lapidus:

On the request of our client we are forwarding a marked draft of the most recently proposed License Agreement between Cytyc Corporation and Deka Products Limited Partnership which reflects your discussion with Dean as confirmed in your letter of September 26..

This draft incorporates two major changes. The first is the grant to Cytyc of certain sublicensing rights. The second change involves the calculation of the 1% royalty on the ThinPrep Processor and related disposables. After discussions with Bruce Fraleigh, we suggest that the original "net sales" concept for determining royalties needs some modification because both the ThinPrep Processors and TransCyt Filters may be components within a larger unit, and the unit appears to be the normal package to be sold to a Cytyc customer. Without some additional clarification, it may be difficult to determine how the different pieces of the unit are priced.

To provide Cytyc with the maximum flexibility in selling and pricing its products (or even services), we have suggested that an "Agreed Sales Price" be used for determining the processor and disposable royalty. The royalty will be based on the number of units sold multiplied by the Agreed Sales Price. The Agreed Sales Price would be subject to periodic review by the parties. The Agreed Sales price has been left blank in each provision and can be filled in by you at a fair price which you and Dean should discuss. Bruce Fraleigh mentioned $18,500 for the hardware and $3.50 for the disposable, but you are the best judge of a fair price.

EXHIBIT
Identified
Received
Admitted

D 02467

If the agreed price concept does not make sense to you, an alternative approach is to determine sales of the processor as a percentage of total hardware sales and sales of the filter as a percentage of total disposable sales.

Sincerely yours,

Stephen B. Hazard

cc: Dean Kamen

g:\mfz\04270\3-002.ltr\101491

PLH DRAFT #1
October 15, 1991

CYTYC/DEKA
LICENSE AGREEMENT

This Agreement is made this ___ day of _____, 19__, between DEKA Products Limited Partnership ("DEKA"), a limited partnership with its principal place of business in Manchester, New Hampshire, and Cytyc Corporation ("Cytyc"), a Delaware corporation with its principal place of business in Marlborough, Massachusetts.

RECITALS

At Cytyc's request, Deka Research & Development Corp. ("R&D"), general partner of DEKA, has assisted Cytyc in the development of a method and apparatus for the controlled instrumented processing of particles with a filter device used for the preparation of slides for medical and laboratory purposes (the "Product Hardware", as defined below). The method and apparatus utilizes pre-existing fluid pumping and control technology owned and developed by DEKA (the "FMS Technology" as defined below) together with certain newly developed technology which provides an improved method and apparatus for quantizing cells and other particles carried in a fluid medium (the "Cytyc Technology" as defined below).

DEKA wishes to license to Cytyc the right to utilize FMS Technology to facilitate the preparation of slides for medical and laboratory purposes. Cytyc is willing to limit the use of both FMS Technology and Cytyc Technology to the preparation of slides for medical and laboratory purposes, and to license back to DEKA the right to use Cytyc Technology for all other purposes, so as to eliminate any possible conflict with other research and development work conducted by DEKA for its own account or for the benefit of others.

NOW, THEREFORE, in consideration of their mutual promises, Cytyc and DEKA agree to the terms and conditions set forth below.

ARTICLE ONE
DEFINITIONS

1.01 Definitions. The following terms wherever used in this Agreement shall have the meanings set forth below:

~~(a) Agreed Sales Price. "Agreed Sales Price" shall have the meaning described to it within Section 3.02 of this Agreement.~~

(~~a~~b) Cytyc Technology. "Cytyc Technology" shall mean the technology reflected in Patent Application CYM-001, Serial Number _____ filed on _____, entitled "Method and Apparatus for Controlled Instrumentation of Particles with a Filter Device" together with all technology incorporated in the Product~~s~~, and together with patents, patent applications and divisions, continuations, continuations-in-part, reexaminations and reissues of any of the foregoing, and all inventions, drawings, prototypes, schematics, trade secrets, know-how, formulae, compositions of matter, designs and intellectual property rights existing that embody or are embodied by, in whole or in part, any of such technology or that pertain to it, including all foreign counterparts to the above, but in all cases excluding and subject to FMS Technology.

(~~b~~c) Field of Use. "Field of Use" shall mean the field of preparing and examining slides for medical or laboratory purposes.

(~~c~~d) FMS Technology. "FMS Technology" shall mean technology reflected in those patents and patent applications listed in Exhibit A attached hereto, now owned by DEKA or in which DEKA has rights, together with patents, patent applications and divisions, continuations, continuations-in-part, reexaminations and reissues of any of the foregoing, and all inventions, drawings, prototypes, schematics, trade secrets, know how, formulae, compositions of matter, designs and other intellectual property rights existing, including all foreign counterparts to any of the above, which incorporate the concepts of such patents owned or controlled by DEKA, which issue or have issued in any jurisdiction in the world upon patent applications which correspond with any of such applications or patents or any divisions, continuation-in-whole or continuation-in-part thereof, and further includes all inventions, drawings, prototypes, schematics, trade secrets, know how, formulae, software, compositions of matter, designs and intellectual property rights existing, developed by DEKA and included within Products.

(~~d~~e) Improvements. "Improvements" shall mean any alteration of the Product~~s~~ made by Cytyc that allows the Product~~s~~ to perform the same or a substantially similar purpose as the Product~~s~~ in a better, more useful or more economical way, or any modification of the Product~~s~~ which permits a better, more useful or more economical means of manufacture of the Product~~s~~.

~~(e) Net Sales. "Net Sales" shall mean the gross sales price and net lease proceeds of Product~~s ~~or Improvements sold or leased by Cytyc or Cytyc's affiliates to unrelated customers,~~

~~less all applicable commissions, discounts and rebates, freight charges and returns and allowances, all if and to the extent allowed in the ordinary course of business and actually stated on Cytyc's [redacted] customer invoice.~~

~~(f) Product Disposables. "Product Disposables" shall mean any filter, cylinders or similar disposables utilized by the Product Hardware.~~

~~(g) Product Hardware. "Product Hardware" shall mean a physical device for the controlled, instrumented processing of particles for the preparation of slides provided such device utilizes the Cytyc Technology, the FMS Technology or both.~~

(~~f~~[redacted]) Person. "Person" shall mean any individual, corporation, association, partnership, joint venture, trust, entity or organization.

(~~g~~[redacted]) Products. "Products" shall mean ~~Product Disposables and Product Hardware~~.

(~~h~~[redacted]) Term. "Term" shall mean the term of this Agreement as contemplated by Article Four hereof.

1.02 General. The terms defined in this Article One shall include the plural, as well as singular.

ARTICLE TWO
LICENSE

2.01 License of FMS Technology. Upon the terms and subject to the conditions set forth herein, DEKA hereby grants to Cytyc, and Cytyc hereby accepts, an exclusive, world-wide license to utilize FMS Technology in the Field of Use for the Term (the "FMS License").

2.02 License of Cytyc Technology. Cytyc shall have the perpetual, world-wide right to utilize Cytyc Technology in the Field of Use. Upon the terms and subject to the foregoing and the conditions hereof, Cytyc hereby grants, and DEKA hereby accepts, the exclusive, world-wide, royalty free license to utilize Cytyc Technology in any and all areas outside the Field of Use (the "Cytyc License").

ARTICLE THREE
ROYALTY

3.01 Royalty. As consideration for the license of FMS Technology ~~during the Term~~, Cytyc agrees to pay DEKA a royalty equal to One Percent (1%) of the Agreed Sales Price for those Products and Improvements, which are manufactured and utilized (other than for promotional or development purposes) by Cytyc and Cytyc's Affiliates during the Term or are sold, leased, or otherwise transferred to customers during the Term by (i) Cytyc and Cytyc's Affiliates, and (ii) any and all sublicensees of Cytyc and Cytyc's Affiliates and any and all sublicensees of such sublicensees ~~of the Net Sales of Product or Improvements.~~

3.02 Agreed Sales Price. Product Hardware is a component of a larger hardware system. The larger hardware system may be distributed by Cytyc in various ways, including but not limited to, outright sales, long-term lease (and short-term rental), consignment, and other ways. Product Disposables may be sold in bundles with other products, and/or may be used by Cytyc as part of a service. To preserve for Cytyc maximum flexibility in packaging, selling and/or bundling its products, all royalties payable to DEKA for Products and Improvements will be based upon an Agreed Sales Price. The "Agreed Sales Price" shall mean [illegible] for Product Hardware and any Improvements thereto and [illegible] for Product Disposables and any Improvements thereto. The Agreed Sales Price shall be reviewed and adjusted by agreement of DEKA and Cytyc at periodic intervals and no less frequently than every three years from the date hereof. Either Cytyc or DEKA may request that the Agreed Sales Price be modified by written notice to the other party, provided the Agreed Sales Price will not be adjusted more frequently than once in any two (2) consecutive year period. The adjustment shall take into account the following factors: (i) the overall value to Cytyc of Product Hardware, Product Disposables, and any Improvements thereto within the context of Cytyc's sales of "ThinPrep TPS System" (and any successor system); (ii) the actual average sales price of Product Hardware, Product Disposables, and any Improvements thereto for the period immediately preceding the adjustment date; and (iii) Cytyc's manufacturing and other costs relative to Product Hardware and Product Disposables.

3.0~~2~~3 Payment. Within forty-five (45) days after the last day of each calendar quarter, Cytyc shall provide DEKA with a written statement prepared for the calendar quarter period ~~just~~ ended which statement shall set forth a ~~as of the applicable last day of each calendar quarter providing a single figure for Net Sales~~breakdown of the number of Products and Improvements sold, leased, or otherwise transferred to customers for the calendar quarter, in question and a calculation of royalties owed. Payment of the royalty due for the applicable calendar quarter shall accompany the statement. The first statement and

payment shall be due after the first calendar quarter period ~~in which the Product is marketed and sold by Cytyc. Pending after the date hereof, and~~ thereafter the report shall be made even if no royalty is due until the end of the Term. All royalties shall be payable in U.S. dollars and sales made in other currencies shall be translated into U.S. dollars at the exchange rate in effect at the end of each applicable calendar quarter.

3.03 Audit. DEKA shall have the right to retain an independent certified public accountant who will during normal business hours and upon reasonable notice (not less than fifteen (15) days), have access to and shall have the right to inspect and make extracts from such documents as may be necessary for the independent auditor to ascertain the accuracy of ~~the single figure of Net Sales~~ Cytyc's statements provided pursuant to Section 3.03 above. An audit may be required once in any calendar year period during the Term and a final audit may be requested at any time within two (2) years following the last day of the Term. DEKA shall be responsible for all costs related to the audit, provided, in the event there has been an underpayment of Cytyc's royalty obligations hereunder in excess of $10,000 for the period which is subject to the audit, Cytyc shall reimburse DEKA for the cost of such audit.

ARTICLE FOUR
TERM AND TERMINATION

4.01 Term of FMS License. The effective date of this Agreement is January 1, 1990 and the term of this Agreement shall extend to the date of the expiration of all of the patents which are the basis of the FMS Technology.

4.02 Term of Cytyc License. The term of the Cytyc License shall be perpetual, unless otherwise terminated as provided herein. The purpose of the perpetual license of Cytyc Technology is to provide DEKA with the unlimited ability to utilize Cytyc Technology outside of the Field of Use without obligation of any kind to Cytyc.

4.03 Termination. The FMS License and Cytyc License only may be terminated as follows:

(a) Upon the mutual written consent of DEKA and Cytyc;

(b) by DEKA on written notice to Cytyc in the event that Cytyc purports to assign this Agreement other than in accordance with Section 13.1 hereof.

Termination shall not relieve Cytyc of its obligation to pay DEKA royalties earned to the date of termination as provided herein.

ARTICLE FIVE
DEKA RESPONSIBILITIES

5.01 Research and Development. DEKA has developed the Products, and Cytyc hereby acknowledges that the Products concept and design are acceptable to Cytyc and that DEKA has fully performed all research and development and all other obligations to Cytyc. Any future research and development responsibilities will be undertaken pursuant to a separate agreement between DEKA and Cytyc, and the consideration for such services shall be separately determined.

5.02 FMS Technology. DEKA shall have the exclusive right and obligation, at its sole expense, to file, procure, maintain and enforce in the U.S. and such other countries as DEKA determines in its sole discretion, patents and patent applications pertaining to FMS Technology. Upon request, DEKA will provide Cytyc with a list of patents and patent applications, U.S. and foreign.

ARTICLE SIX
CYTYC OBLIGATIONS

6.01 Sales. Cytyc agrees to use all reasonable efforts consistent with Cytyc's overall business objectives to maximize the sales of Products or Improvements. DEKA acknowledges that the sale of Products or Improvements may be regulated by various governmental authorities, and that significant amounts of time may be necessary for regulatory compliance and/or to develop appropriate marketing, sales and manufacturing capabilities.

6.02 Cytyc Technology. Cytyc shall have the exclusive right and obligation, at its sole expense, to file, procure, maintain and enforce in the U.S. and such other countries as Cytyc determines in its sole discretion, patents and patent applications pertaining to Cytyc Technology. Upon request, Cytyc will provide DEKA with a list of patents and patent applications, U.S. and foreign.

ARTICLE SEVEN
CONFIDENTIALITY

7.01 Confidentiality. All technical data and know-how regardless of the form, pertaining or relating to, the FMS Technology and Cytyc Technology (whether tangible or intangible) including without limitation, each and every invention, trade secret, formula, process, routine, technique, concept, method or idea, and all software and related documentation in any state of development (including, but not limited to, source code, object code, flow charts, diagrams and other materials of any type whatsoever) and all rights of any kind in or to any of the

foregoing (including without limitation copyrights, trade secret rights and patents) regardless of whether any or all of the foregoing constitutes copyrightable or patentable subject matter communicated to one party to the other under this Agreement shall be kept confidential. Each party shall take all reasonable steps to ensure that such confidential information does not pass negligently or otherwise into the hands of those unauthorized to receive it, and that such confidential information is not used for any purpose not authorized by this Agreement or other written agreement between the parties. Notwithstanding the foregoing, a party shall be relieved of the confidentiality obligations herein and not be prevented by this Agreement from utilizing any information received by it from any other party if:

(i) the information is or becomes generally available to the public through no fault of the receiving party;

(ii) the information is acquired in good faith in the future by the receiving party from a third party who is not under an obligation of confidence with respect to such information;

(iii) is required to be disclosed by any applicable judgment, order or decree of any court or governmental body or agency having jurisdiction or by any law, rule or regulation (including without limitation, any such securities law, rule or regulation relating to offerings of securities or periodic reporting requirements), provided that in connection with any such disclosure, the party disclosing such information shall give to the other party reasonable prior notice of the disclosure of any such information pursuant to this exception and shall obtain, to the extent possible, confidential treatment for such information by any authority requiring delivery of such information; or

(iv) the disclosure of such information is necessary for the commercial exploitation of any License granted hereunder and the party to whom such information is being disclosed is advised of the confidential and proprietary nature of such information and agrees to be bound by appropriate confidentiality and non-disclosure agreements which prescribe the unauthorized disclosure or use of such information.

7.02 Survival After Termination. Notwithstanding any termination of this Agreement, the obligations of the parties with respect to the protection and nondisclosure of confidential information shall survive and continue to be enforceable.

ARTICLE EIGHT
INFRINGEMENT

8.01 (a) DEKA and Cytyc shall keep each other fully informed on a current basis, of the circumstances and details of any actual or potential infringements of FMS Technology and Cytyc Technology as utilized in the Products or Improvements of which they become aware. Cytyc, in the event of any actual or potential infringement of FMS Technology and/or Cytyc Technology as utilized in the Products or Improvements, shall have the right, but not the obligation, to institute suit against such actual or potential infringer and DEKA (at DEKA's expense) shall fully cooperate with Cytyc in any such action in the event the claimed infringement involves FMS Technology. In connection therewith, Cytyc may, at its sole election, require that DEKA join with Cytyc as a party to any infringement action brought by Cytyc hereunder. Cytyc shall bear all expenses associated with the foregoing. In addition, DEKA may, at its election, participate in any such action with counsel of its own choosing and at its own expense. Any recovery as a result of such action shall first be paid over to Cytyc and DEKA, pro rata in accordance with the reasonable expenses incurred by such parties (including, without limitation, reasonable fees and disbursements of counsel) up to the full aggregate amount of such expenses, and any additional recovery shall be allocated as hereafter provided. Cytyc and DEKA agree that in any suit including claims of FMS Technology and Cytyc Technology under this paragraph 8.01(a), they will request that a special verdict or other appropriate order or determination be made so as to specify those damages included in such ruling attributable to Cytyc and DEKA, respectively. In the event that no such ruling is made, Cytyc and DEKA shall negotiate in good faith to determine the manner in which such damages shall be allocated, and if Cytyc and DEKA fail to agree within thirty (30) days following the receipt of the proceeds of the recovery, the allocation shall be determined by arbitration as provided herein.

(b) DEKA agrees that Cytyc shall have the sole power to take legal action or other action (other than as contemplated by Sections 8.01(a) and 8.02 hereof) before any court or governmental authority with respect to infringement or other protection of the FMS Technology and Cytyc Technology utilized in Products or Improvements. Notwithstanding the provisions of this subsection 8.01(b), if Cytyc does not institute suit against an infringer within one hundred twenty (120) days after notice thereof by DEKA to Cytyc of DEKA's desire to do so and if the circumstances and details of such infringement to the extent then known by DEKA, DEKA shall have the right to institute an action, with counsel of its own choosing, and may, at its sole election, require that Cytyc join with DEKA as a party to any such action. DEKA shall bear all expenses associated with actions undertaken

pursuant to the foregoing sentence. Any recovery as a result of any action shall first be paid to Cytyc to the extent of all reasonable expenses incurred by Cytyc (including, without limitation, reasonable fees and disbursements of counsel) and the balance, if any, shall be paid over to DEKA.

(c) In the event Cytyc shall institute an action pursuant to Section 8.01(a) hereof and thereafter elects to abandon the same, Cytyc shall give timely notice to DEKA, which may, if it so desires, continue the litigation of such action in which event, for purposes of this Agreement, shall be deemed to have been instituted pursuant to paragraph 8.01(b) hereof.

8.02 With regard to any legal action instituted by Cytyc or DEKA pursuant to Section 8.01 above, the party instituting such action shall have the right to settle any disputes with third parties relating to the FMS Technology or Cytyc Technology as incorporated in Products or Improvements, provided, however, that if such settlement would result in the grant of rights to any Person that would diminish or dilute the License granted to DEKA hereunder or the rights of Cytyc in the FMS Technology, as the case may be, then no such settlement shall be agreed to without the prior consent of the party whose rights are so affected.

ARTICLE NINE
REPRESENTATIONS, WARRANTIES AND COVENANTS

9.01 Cytyc represents, warrants and covenants to DEKA as follows:

(a) Existence and Authority. Cytyc is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Cytyc is qualified to do business in Massachusetts as a foreign corporation.

(b) Authorization of Agreement. The execution, delivery and performance of this Agreement by Cytyc and the consummation of the transactions and agreements contemplated hereby have been duly and validly authorized by all necessary corporation action of Cytyc. This Agreement has been duly and validly executed and delivered by Cytyc and constitutes the valid and binding obligation of Cytyc, enforceable in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium or other laws relating to creditors' rights generally, and subject to the availability of specific performance and injunctive and other forms of equitable relief.

(c) Effect of Agreement, Etc. The execution, delivery and performance of this Agreement by Cytyc and consummation by it of the transactions contemplated hereby, do not, with or without the giving of notice and the lapse of time, or both, (i) violate any provision of law, statute, rule, regulation or executive

order to which Cytyc is subject; (ii) violate any judgment, order, writ or decree of any court to which Cytyc is subject; or (iii) result in the breach of or conflict with any term, covenant, condition or provisions of, result in or permit any other party to cause the modification or termination of, constitute a default under, or result in the creation or imposition of any lien, security interest, charge or encumbrance upon any of the Cytyc Technology pursuant to any partnership agreement, corporate charter document or, to the best knowledge of Cytyc, any commitment, contract or other agreement or instrument to which Cytyc is a party.

(d) Title to Cytyc Technology. The Cytyc Technology is owned by Cytyc free of all liens, claims and encumbrances, and the use of the Cytyc Technology and, to the best of Cytyc's knowledge, the grant of the DEKA License as contemplated hereby will not interfere with the rights of any third party, and no infringement of the Cytyc Technology is known to Cytyc. The patent (patent application) which is part of the Cytyc Technology has been maintained and has not been abandoned in any jurisdiction through nonuse or nonpayment of fees, annuities, taxes or the like and has not lapsed, expired or been opposed or cancelled or been the subject of a re-examination request in any jurisdiction.

9.02 DEKA represents and warrants to Cytyc as follows:

(a) Organization, Etc. DEKA is a limited partnership validly existing and in good standing under the laws of the State of New Hampshire.

(b) Authorization of Agreement. The execution, delivery and performance of this Agreement and any agreements contemplated hereby by DEKA have been duly and validly authorized by all necessary action, including all necessary corporate action of DEKA Research & Development Corporation, the sole general partner of DEKA. This Agreement has been duly and validly executed and delivered by DEKA and constitutes the valid and binding obligation of DEKA, enforceable in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium or other laws relating to creditors' rights generally, and subject to the availability of specific performance and injunctive and other forms of equitable relief.

(c) Effect of Agreement, Etc. The execution, delivery and performance of this Agreement by DEKA and consummation by DEKA of the transactions contemplated hereby, will not, with or without the giving of notice and the lapse of time, or both, (i) violate any provision of law, statute, rule, regulation or executive order to which DEKA is subject; (ii) violate any judgment, order, writ or decree of any court to which DEKA is subject; or (iii) result in the breach or conflict with any term,

covenant, condition or provision, result in or permit any other party to cause the modification or termination of, constitute a default under, or result in the creation or imposition of any lien, security interest, charge or encumbrance upon any of the FMS Technology pursuant to any partnership agreement, or to the best knowledge of DEKA, any commitment, contract or other agreement or instrument to which DEKA is a party.

(d) Title to FMS Technology. The FMS Technology within the Field of Use is owned by DEKA, free of all liens, claims and encumbrances, and, to the best of DEKA's knowledge, the use of the FMS Technology within the Field of Use and the grant of the license to utilize FMS Technology as contemplated hereby will not interfere with the rights of any third party, and no infringement of the FMS Technology within the Field of Use is known to DEKA. The patents which are part of the FMS Technology have been maintained and have not been abandoned in any jurisdiction through nonuse or nonpayment of fees, annuities, taxes or the like and have not lapsed, expired or been opposed or cancelled or been the subject of a re-examination request in any jurisdiction.

ARTICLE TEN
INSURANCE AND INDEMNIFICATION

10.1 During the term of this License Agreement, Cytyc shall and shall cause each permitted or approved assignee or sublicensee to, at its or their own cost and expense, procure and maintain, product liability insurance against claims for personal injury and property damage caused by or occurring in connection the Products or Improvements, with limits of not less than $1 million per occurrence of loss or damage. Such policies of insurance shall name DEKA and/or its designees as an additional insured and shall provide that such policies shall not be cancelled except on not less than twenty (20) days prior written notice to DEKA.

10.2 Cytyc agrees to defend and indemnify and hold DEKA harmless against and from any and all liabilities, obligations, damages, penalties, claims, costs, charges, and expenses, including without limitation, reasonable attorneys' fees, which may be imposed upon or incurred by or asserted against DEKA by reason of claims asserted by others, which arise out of the manufacture, use or sale of any Products or Improvements, which claims are not fully covered by insurance maintained by Cytyc as provided in Section 10.1.

ARTICLE ELEVEN
NOTICES

11.1 Notices. All notices or communications required or

permitted by this Agreement shall be in writing and shall be sufficiently given if delivered or mailed by United States registered or certified mail, postage prepaid, return receipt requested, or delivered by an overnight delivery service, to the following addresses:

If to DEKA: Deka Research & Development Corp.,
General Partner
Deka Products Limited Partnership
340 Commercial Street
Manchester, New Hampshire 03101
Attention: President

If to Cytyc: Cytyc Corporation
237 Cedar Hill Street
Marlborough, MA 01752
Attention: President

Any party may change its address by written notice to the other party. All notices shall be deemed to have been given as of the date mailed or delivered to the overnight delivery service.

ARTICLE TWELVE
DISPUTES

12.1 Arbitration. Cytyc and DEKA agree that any dispute, controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be settled by arbitration to be conducted in Manchester, New Hampshire, in accordance with the Commercial Arbitration Rules of the American Arbitration Association, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. Cytyc and DEKA also agree that the arbitrator(s) shall have the right to assess the losing party with the legal fees and expenses of both parties.

12.2 Injunctive Relief. Notwithstanding Section 12.1, Cytyc and DEKA agree that in the event of a violation of, or a dispute arising under, the confidentiality provisions of Article Seven, a party may bring an action to obtain injunctive or other appropriate relief in any court having jurisdiction thereof.

ARTICLE THIRTEEN
MISCELLANEOUS

13.1 Assignment and Sublicenses. Cytyc may grant sublicenses hereunder, provided that any such sublicense contains confidentiality and infringement provisions substantially the same as those contained in Articles SEVEN and EIGHT. Neither this Agreement nor any of the rights or obligations hereunder, including, without limitation, the licensed technology, may be

assigned by either party without the prior written consent of the other party, which will not be unreasonably withheld; provided that Cytyc may assign its rights under this Agreement in connection with a sale of all or substantially all of its assets in a single transaction or series of related transactions to a single purchaser provided that such purchaser agrees in writing to be bound by all obligations of Cytyc hereunder.

13.2 Successors and Assigns. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their successors and permitted assigns.

13.3 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New Hampshire.

13.4 Headings. The headings contained in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement.

13.5 Entire Agreement. This Agreement constitutes the entire understanding of the parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating thereto. No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by the parties.

13.6 Counterparts. This Agreement may be executed in one or more counterparts, all of which taken together will constitute one and the same instrument.

13.7 Further Assurances. The parties agree to execute and deliver promptly to each other all such further instruments and documents as may reasonably be requested to carry out fully the intent, and to accomplish the purposes, of the transactions referred to herein.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date written above.

DEKA PRODUCTS LIMITED PARTNERSHIP

By: DEKA RESEARCH & DEVELOPMENT CORP., General Partner

By:_____
Dean Kamen, President

CYTYC CORPORATION

By:_____
Stanley Lapidus, President

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EXHIBIT 19

DEKA

May 11, 1990

Mr. Stanley N. Lapidus
Cytyc Corp.
237 Cedar Hill Street
Marlborough, Massachusetts 01752

Dear Stanley:

I am enclosing two copies of this letter, which has been revised to reflect your concerns as expressed in your memo to me dated April 26, 1990, to serve as a "Letter of Intent" covering the points we have agreed to. If this reflects your understanding of our agreement, please sign and return one copy to me. After that we can have the lawyers draw up a formal Agreement.

LETTER OF INTENT

Royalty:

Cytyc agrees to grant to Dean Kamen a royalty of one percent (1%) of net sales on:

- Sample preparation instruments using the FMS Licensed Technology
- Disposables using the FMS Licensed Technology (currently consisting of a molded plastic mandrel and an attached filter).

Vials filled with collection medium are explicitly excluded from this Agreement. The dollar amount for determination of the royalty shall be the net sales price. This means that if you discount to distributors, dealers, or end users, the royalty will reflect the discounted price.

Equity:

Cytyc agrees to sell Dean Kamen 63,196 shares of the Company's common stock at a price of $.10 per share. This represents one percent (1%) of the total common shares and

DEKA RESEARCH & DEVELOPMENT CORP.
Technology Center, 340 Commercial Street
Manchester, New Hampshire 03101-1108 • (603) 669-5139

EXHIBIT
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converted preferred shares of the Company's authorized and outstanding stock as of March 1, 1990.

Cytyc agrees that $.10 per share is the current fair market value of its Common Stock and Cytyc will not take any position inconsistent with this. Furthermore, you agree to have Cytyc take any and all corporate actions, including seeking shareholder approval if necessary, to authorize the sale of stock to Dean Kamen.

The shares which will be purchased will be subject to the restrictions on voluntary transfer, requiring that Cytyc and certain existing shareholders be given an opportunity to match an offer from an outside investor, set forth in Exhibit A hereto provided, however, that all shares of common stock of Cytyc currently and subsequently issued are subject to the same restriction. In addition, Dean Kamen shall have piggyback registration rights for the shares purchased. These rights shall be the same as those provided to purchasers of Cytyc Preferred Stock in the last financing (March 1989) done by Cytyc, a copy of which rights are set forth in Exhibit B hereto.

Licensing:

Dean Kamen and/or Deka will grant to Cytyc an exclusive, irrevocable, world-wide license to use Deka's FMS technology for preparation of slides for medical or laboratory purposes.

Cytyc will grant to Deka and/or Dean Kamen an exclusive, irrevocable, world-wide license to use the technology developed by Cytyc and Deka as embodied in a Patent Application CYM-001, entitled "Method and Apparatus for Controlled Instrumentation of Particles with a Filter Device" for any purpose other than for preparation of slides for medical or laboratory purposes.

Please give me a call if you want to discuss any of the above.

Sincerely,

Dean Kamen, President

ACCEPTED AND AGREED:

CYTYC CORP.

By _____
Stanley N. Lapidus
Its President

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